Learn about 8 patients in the ERIVANCE trial and why they were eligible for treatment with Erivedge® (vismodegib)

Erivedge was studied in ERIVANCE, a pivotal trial[1,2]

ERIVANCE was a Phase II, international, single-arm, 2-cohort, open-label trial that demonstrated clinically meaningful benefit in advanced basal cell carcinoma (BCC). The trial was conducted in 104 patients with either metastatic BCC (mBCC) (n=33) or locally advanced BCC (laBCC) (n=71). Of the 104 patients enrolled, 96 were evaluable for objective response rate (ORR) and were treated with Erivedge 150 mg once per day orally until disease progression, intolerable toxicity, or withdrawal from study. Patients were seen at baseline and every 4 weeks for safety monitoring, and every 8 weeks for response assessment.

Objective response rate by independent review from ERIVANCE[1]*

	laBCC (n=63)	mBCC (n=33)
ORR	43% (n=27)	30% (n=10)
(95% CI)	(30.5-56.0)	(15.6-48.2)
Complete response	21% (n=13)	0% (n=0)
Partial response	22% (n=14)	30% (n=10)
Median duration of response (months)	7.6	7.6
(95% CI)	(5.7-9.7)	(5.6-NE)

*Patients received at least 1 dose of Erivedge with independent pathologist-confirmed diagnosis of BCC. Locally advanced BCC patients were considered responders if they did not experience progression and had ≥30% reduction in lesion size (sum of the longest diameter) from baseline in target lesions by radiography or in externally visible dimensions of target lesions (scar tissue was measured); or had complete resolution of ulceration in all target lesions. Complete response was objective response with no residual BCC on sampling biopsy. Partial response was objective response with presence of residual BCC on sampling biopsy. In the metastatic BCC cohort, response was assessed according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.0. Complete response was disappearance of all target and nontarget lesions. Partial response was ≥30% decrease in SLD of target lesions from baseline.

CI=confidence interval; laBCC=locally advanced BCC; mBCC=metastatic BCC; NE=not estimable; SLD=sum of the longest diameter.

Incidence of common adverse reactions (≥10%): Pooled analysis of 4 studies (N=138)[1,3,4]

Adverse reactions occurring in ≥10% of advanced BCC patients	Grade 1 (%) (Mild)	Grade 2 (%) (Moderate)	Grade 3 (%) (Severe)	Grade 4 (%) (Disabling or life-threatening)	All grades (%)
Muscle spasms	51.4%	16.7%	3.6%	–	72%
Alopecia	49.3%	14.5%	N/A	N/A	64%
Change in taste (dysgeusia)	34.1%	21.0%	N/A	N/A	55%
Weight loss	25.4%	12.3%	7%	N/A	45%
Fatigue	27.5%	6.5%	5%	0.7%	40%
Nausea	23.9%	5.8%	0.7%	–	30%
Diarrhea	21.7%	6.5%	0.7%	–	29%
Decreased appetite	15.2%	8.0%	2.2%	–	25%
Constipation	17.4%	3.6%	–	–	21%
Arthralgias	11.6%	3.6%	0.7%	–	16%
Vomiting	10.9%	2.9%	–	–	14%
Loss of taste (ageusia)	8.0%	2.9%	N/A	N/A	11%

Adverse reactions reported using *Medical Dictionary for Regulatory Activities* preferred terms and graded using *National Cancer Institute Common Terminology Criteria for Adverse Events v3.0* for assessment of toxicity.
N/A=not applicable, this grade does not exist for this adverse reaction.

Indication

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

Boxed Warning

EMBRYO-FETAL TOXICITY

- **Erivedge can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Erivedge is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations**
- **Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge. Advise pregnant women of the potential risks to a fetus. Advise females of reproductive potential to use effective contraception during and after Erivedge**
- **Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential**

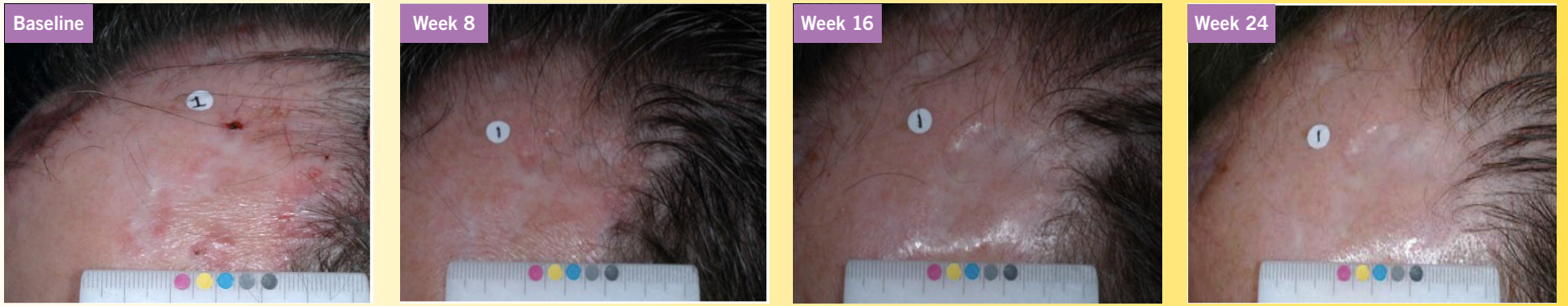
Please see full Prescribing Information, including the **BOXED WARNING** and the Medication Guide, for a complete discussion of the risks associated with Erivedge.

Erivedge® (vismodegib) capsule

COMPLETE RESPONDER FROM THE ERIVANCE TRIAL

Peter, a 51-year-old with locally advanced BCC[3]

Scalp: Superficial and nodulocystic BCC



Peter's history of BCC

- Peter was initially diagnosed with BCC in 1986
- He underwent shave biopsies on the scalp in 2007 and 2008

Reasons why Peter was eligible for treatment with Erivedge

- Surgery was medically contraindicated because of recurrent BCC that was unlikely to be curatively resected as well as anticipated substantial morbidity and/or deformity
- Radiotherapy was considered contraindicated because of Gorlin syndrome

Treatment

- Peter started treatment with Erivedge in May 2009 and was treated for 18.6 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- He continued treatment as of the data cutoff in November 2010

Clinical outcome

- Peter experienced a complete response, as assessed by independent review
  - Complete response is defined as objective response with no residual BCC on sampling biopsy
- The sampling biopsy at Week 24 did not show evidence of residual BCC

Treatment-related adverse reactions

- Peter experienced ageusia, alopecia, arthralgia, diarrhea, fatigue, folliculitis, abnormal hair growth, hypokalemia, muscle spasms, and decreased weight

ERIVANCE patient eligibility is based on study investigator assessment. Case study shows results of treatment in a specific patient and case was last verified at clinical data cutoff. Individual results may vary. This case is for general informational purposes only and is not intended to convey medical advice. You should use your independent medical judgment in the diagnosis and treatment of your patients.

EMBRYO-FETAL TOXICITY (cont'd)

- Females of Reproductive Potential: Use contraception during therapy with Erivedge and for 24 months after the final dose
- Males: Use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female partners of reproductive potential during and for 3 months after the final dose of Erivedge. Do not donate semen during and for 3 months after the final dose of Erivedge
- Blood Donation: Advise patients not to donate blood or blood products while receiving Erivedge and for 24 months after the final dose of Erivedge
- Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at (888) 835-2555

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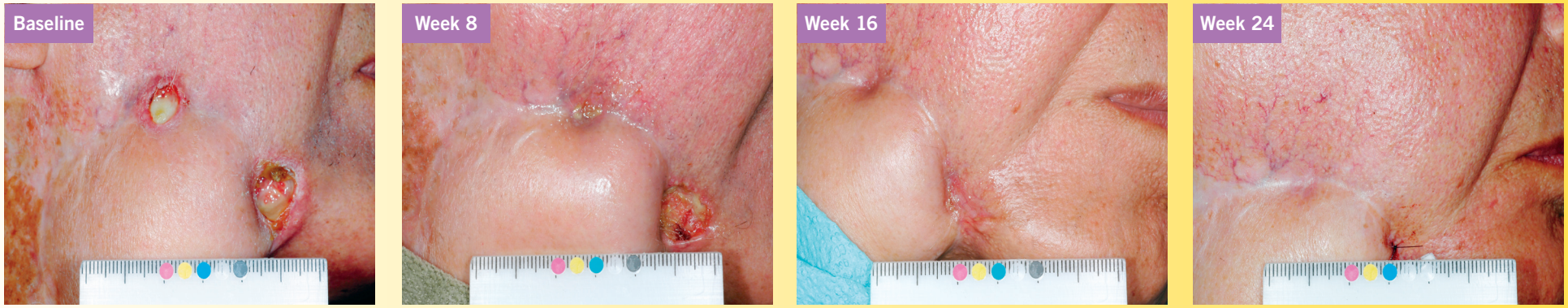
Erivedge® (vismodegib) capsule

PARTIAL RESPONDER FROM THE ERIVANCE TRIAL

James, a 79-year-old with locally advanced BCC[3]

Right neck, the masticator space: Nodular and infiltrative BCC



James' history of BCC

- James was initially diagnosed with BCC in 2004
- He underwent excisions on the neck in 2004, 2006, and 2008

Reasons why James was eligible for treatment with Erivedge

- Tumor was in the masticator space and was considered to be inoperable
- Radiotherapy had been previously administered to the lesion

Treatment

- James started treatment with Erivedge in October 2009 and was treated for 11.7 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- He discontinued therapy in October 2010 due to disease progression

Clinical outcome

- James experienced a partial response, as assessed by independent review
  - Partial response is defined as objective response with presence of residual BCC on sampling biopsy
- At Week 24, sampling biopsy from the neck lesion showed no BCC
  - Partial response in this case was based on MRI findings, as assessed by RECIST*

Treatment-related adverse reactions

- James experienced chills, decreased appetite, dysgeusia, dyspepsia, fatigue, musculoskeletal pain, nausea, and rhinorrhea
- He had 3 dose interruptions for 2 adverse reactions (dysgeusia and musculoskeletal pain). He experienced 79 days without treatment†
  - Per Erivedge USPI, withhold Erivedge for up to 8 weeks for intolerable adverse reactions until improvement or resolution

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*Response Evaluation Criteria in Solid Tumors.

†In ERIVANCE, patients were allowed to interrupt drug treatment for reasons other than managing intolerable adverse reactions.

Additional Important Safety Information

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during treatment with Erivedge. Permanently discontinue Erivedge in patients with these reactions

Premature Fusion of the Epiphyses

- Premature fusion of the epiphyses has been reported in pediatric patients exposed to Erivedge. In some cases, fusion progressed after drug discontinuation. Erivedge is not indicated for pediatric patients

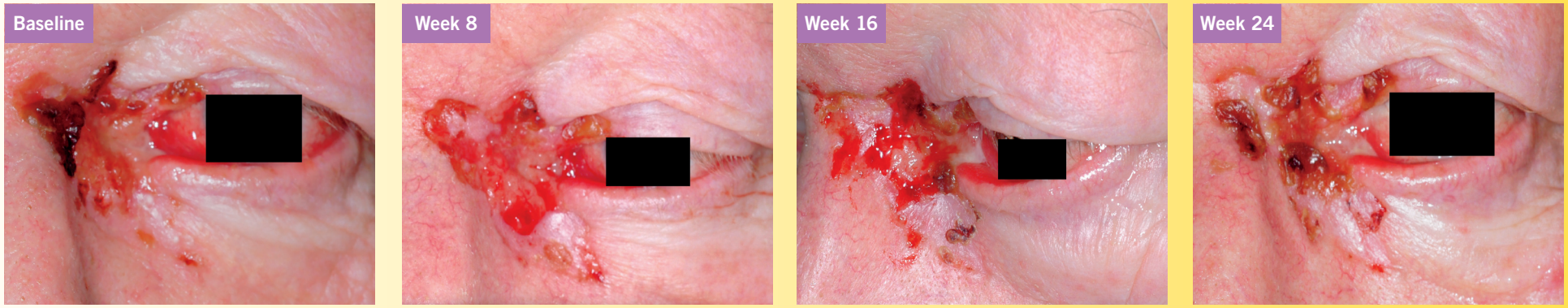
Please see full Prescribing Information, including the **BOXED WARNING** and the Medication Guide, for a complete discussion of the risks associated with Erivedge.

Erivedge® (vismodegib) capsule

NON-RESPONDER FROM THE ERIVANCE TRIAL

George, a 69-year-old with locally advanced BCC[3]

Left eye, internal (medial) canthus: Nodular and infiltrative BCC



George's history of BCC

- George was initially diagnosed with BCC in 2009
- No prior treatment was reported

Reasons why George was eligible for treatment with Erivedge

- George was not a candidate for surgery because the lesion was considered inoperable
- Radiotherapy was considered to be inappropriate because of the location of the lesion

Treatment

- George started treatment with Erivedge in October 2009 and was treated for 10 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- He discontinued therapy in August 2010 as a result of an adverse event unrelated to treatment with Erivedge

*Response Evaluation Criteria in Solid Tumors.

Clinical outcome

- George experienced a non-response, as assessed by independent review
  - Patients were considered non-responders if they met any of the following criteria:
    - <30% decrease in size of target lesions or ≥20% increase in size of target lesions (scar tissue was included in measurement of lesion)
    - New ulceration of lesions persisting without evidence of healing for at least 2 weeks
    - New lesions by radiographic assessment or physical examination
    - Progression of non-target lesions by RECIST*
- The sampling biopsy at Week 24 showed evidence of residual BCC

Treatment-related adverse reactions

- George experienced muscle spasms, alopecia, ageusia, and asthenia

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Adverse Reactions

- The most common adverse reactions (≥10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia
- Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown. In clinical trials, 30% of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia (4%), azotemia (2%), and hypokalemia (1%)
- Additionally, in a post-approval clinical trial conducted in 1232 patients with locally advanced or metastatic BCC treated with Erivedge, a subset of 29 patients had baseline values for blood creatine phosphokinase (CPK) reported. Within the subset of patients, 38% had a shift from baseline, including Grade 3 (3%) increased CPK. Grade 3 or 4 increased CPK occurred in 2.4% of the 453 patients across the entire study population with any CPK measurement
- Adverse reactions identified during post-approval use: drug-induced liver injury, Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms

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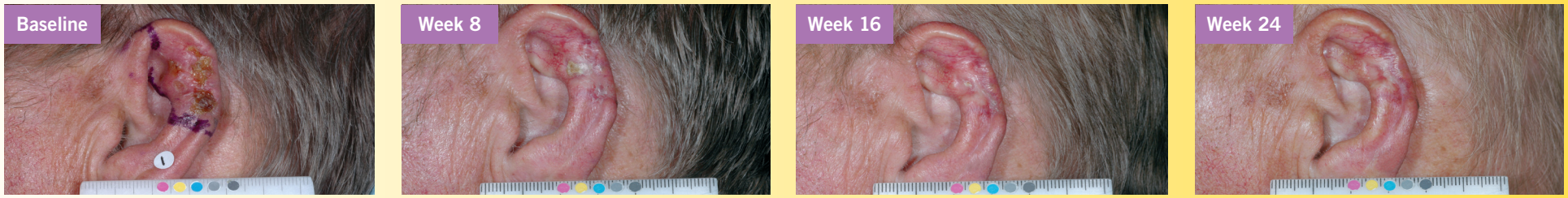
Erivedge® (vismodegib) capsule

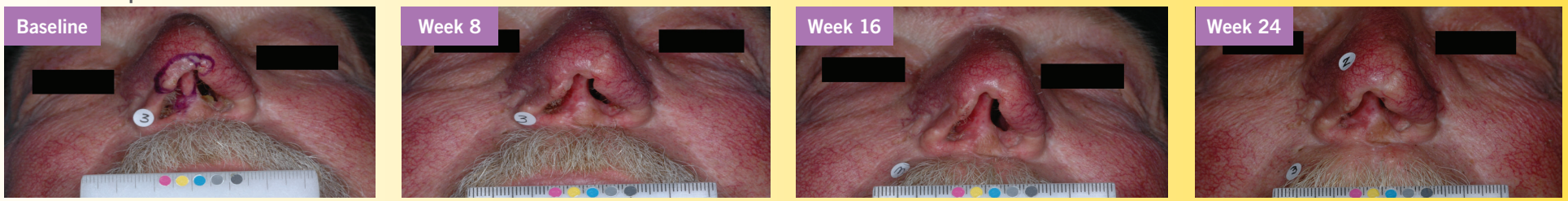
COMPLETE RESPONDER FROM THE ERIVANCE TRIAL

Stanley, a 66-year-old with locally advanced BCC[3]

Left ear: Infiltrative BCC



Distal nasal tip: Nodular and micronodular BCC



Stanley's history of BCC

- Stanley was initially diagnosed with BCC in 1999 and subsequently underwent several excisions on the nose

Reasons why Stanley was eligible for treatment with Erivedge

- Surgery was medically contraindicated because of anticipated substantial morbidity and/or deformity
- Radiotherapy was considered contraindicated because of the risk of deformity

Treatment

- Stanley started treatment with Erivedge in December 2009 and was treated for 8.6 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- In September 2010, treatment was discontinued at his request

*In ERIVANCE, patients were allowed to interrupt drug treatment for reasons other than managing intolerable adverse reactions.

Clinical outcome

- Stanley experienced a complete response, as assessed by independent review
  - Complete response is defined as objective response with no residual BCC on sampling biopsy
- The sampling biopsy at Week 24 did not show evidence of residual BCC

Treatment-related adverse reactions

- Stanley experienced ageusia, alopecia, muscle spasms, and weight loss
- Stanley had a dose interruption for 1 adverse reaction (muscle spasms). He experienced 24 days without treatment*
  - Per Erivedge USPI, withhold Erivedge for up to 8 weeks for intolerable adverse reactions until improvement or resolution

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Use in Specific Populations

Lactation

- No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise women that breastfeeding is not recommended during therapy with Erivedge and for 24 months after the final dose

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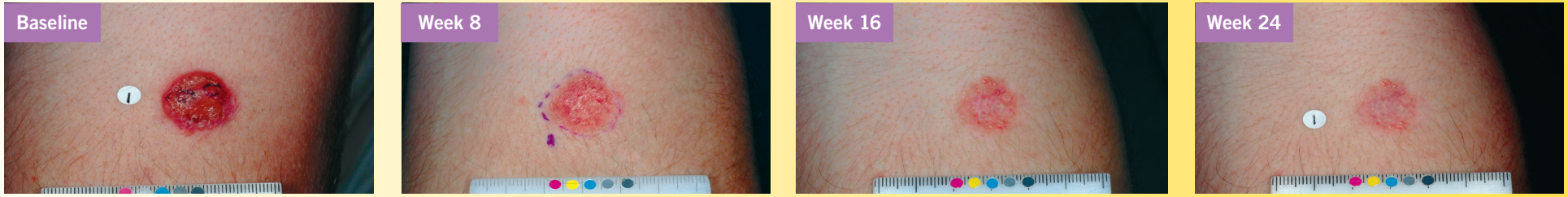
Erivedge® (vismodegib) capsule

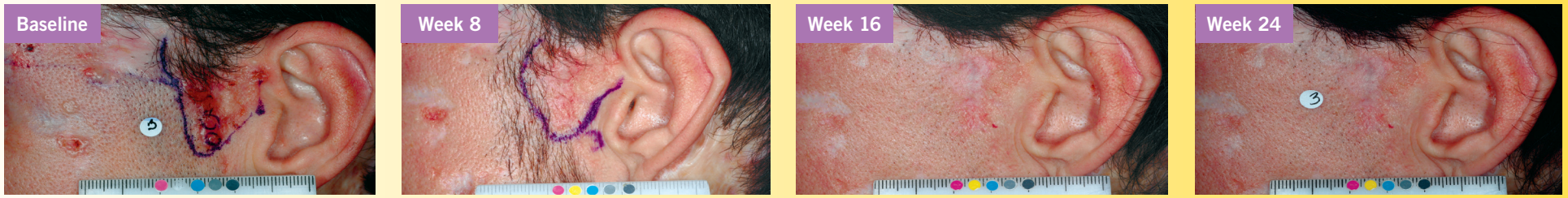
PARTIAL RESPONDER FROM THE ERIVANCE TRIAL

Robert, a 34-year-old with locally advanced BCC[3]

Left brachium: Nodular BCC with focal infiltrative



Left lateral temple: Nodular BCC



Robert's history of BCC

- Robert was initially diagnosed with BCC in 1985
- He underwent multiple procedures between 2006 and 2009, including:
  - Mohs surgery on the left temporal scalp, right medial eyebrow, right postauricular area, and right mandibular neck in 2006
  - Mohs surgery on the left mastoid area of the neck, left postauricular area, left lateral canthus, left lateral eyelid canthus, and repair of left eye defect (with graft and flaps) in 2007
  - Excisions on the left lower eyelid and medial canthus with repair of defect using graft from right upper eyelid in 2009

Reasons why Robert was eligible for treatment with Erivedge

- Surgery was medically contraindicated because of anticipated substantial morbidity and/or deformity
- Radiotherapy was considered contraindicated because of Gorlin syndrome

Treatment

- Robert started treatment with Erivedge in October 2009 and was treated for 13.2 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- He continued on treatment as of the data cutoff in November 2010

Clinical outcome

- Robert experienced a partial response, as assessed by independent review
  - Partial response is defined as objective response with presence of residual BCC on sampling biopsy
- At Week 24, sampling biopsies were performed on the lesions:
  - Histology of the arm lesion was consistent with BCC
  - All other lesions depicted did not show evidence of BCC

Treatment-related adverse reactions

- Robert experienced alopecia, fatigue, muscle spasms, and weight loss

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Boxed Warning

EMBRYO-FETAL TOXICITY

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- **Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge. Advise pregnant women of the potential risks to a fetus. Advise females of reproductive potential to use effective contraception during and after Erivedge**
- **Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential**

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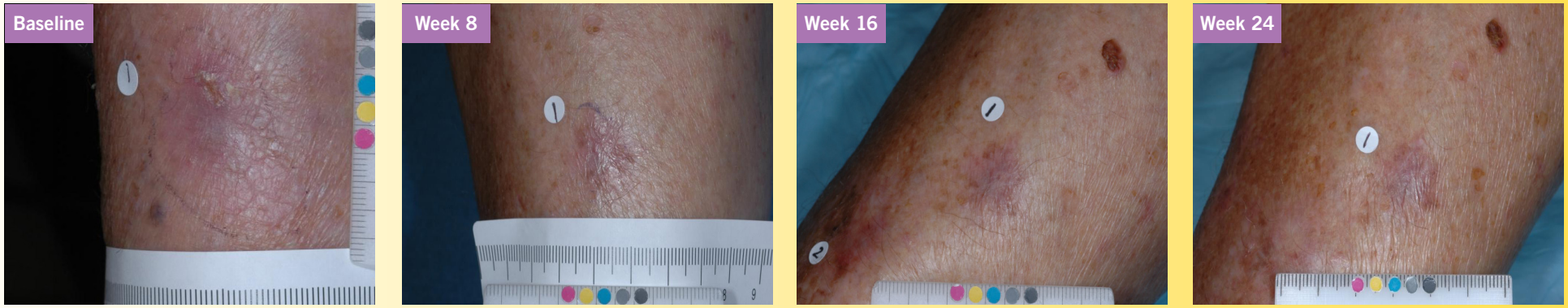
Erivedge® (vismodegib) capsule

NON-RESPONDER FROM THE ERIVANCE TRIAL

Marsha, a 75-year-old with locally advanced BCC[3]

Left leg mid-shin: Superficial and nodular BCC



Marsha's history of BCC

- Marsha was initially diagnosed with BCC in 1990
- She underwent excisions between 1990 and 2009, including excisions of lesions on the legs in 1990, 1995, 2007, and 2009

Reasons why Marsha was eligible for treatment with Erivedge

- Surgery was medically contraindicated because of anticipated substantial morbidity and/or deformity
- Radiotherapy was considered to be inappropriate because of the high number of lesions, scarring side effects of radiation therapy, and risk of recurrence of cancer because of increased exposure to radiation

Treatment

- Marsha started treatment with Erivedge in November 2009 and was treated for 12.5 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- She continued on treatment as of the data cutoff in November 2010

Clinical outcome

- Marsha experienced a non-response, as assessed by independent review
  - Patients were considered non-responders if they met any of the following criteria:
    - <30% decrease in size of target lesions or ≥20% increase in size of target lesions (scar tissue was included in measurement of lesion)
    - New ulceration of lesions persisting without evidence of healing for at least 2 weeks
    - New lesions by radiographic assessment or physical examination
    - Progression of non-target lesions by RECIST*
- The sampling biopsy at Week 24 showed evidence of residual BCC

Treatment-related adverse reactions

- Marsha experienced decreased appetite, hypogeusia, muscle spasms, and decreased weight

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*Response Evaluation Criteria in Solid Tumors.

EMBRYO-FETAL TOXICITY (cont'd)

- Females of Reproductive Potential: Use contraception during therapy with Erivedge and for 24 months after the final dose
- Males: Use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female partners of reproductive potential during and for 3 months after the final dose of Erivedge. Do not donate semen during and for 3 months after the final dose of Erivedge
- Blood Donation: Advise patients not to donate blood or blood products while receiving Erivedge and for 24 months after the final dose of Erivedge
- Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at (888) 835-2555

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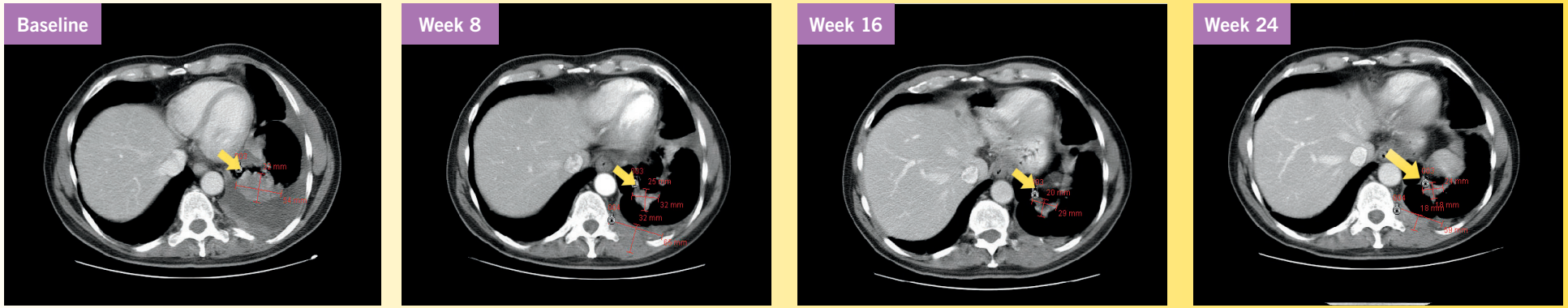
Erivedge® (vismodegib) capsule

Frank, a 54-year-old with metastatic BCC[3]

Lung: Metastatic BCC



Frank's history of BCC

- Frank was initially diagnosed with BCC in 2005
- He underwent multiple surgeries (right ear, right mastoid bone, and right temporal bone) and multiple biopsies (right neck node, lung nodule)
- He had radiation directed to the right ear canal in 2005
- He received treatment for metastatic disease in 2009

Treatment

- Frank started treatment with Erivedge in June 2009 and was treated for 9.5 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- In March 2010, treatment was discontinued because of disease progression

Clinical outcome

- Frank experienced a partial response, as assessed by independent review
  - Partial response is defined as ≥30% decrease in sum of longest diameter of target lesions from baseline

Treatment-related adverse reactions

- Frank experienced alopecia, dysgeusia, muscle spasms, nail disorder, and nausea

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Additional Important Safety Information

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during treatment with Erivedge. Permanently discontinue Erivedge in patients with these reactions

Premature Fusion of the Epiphyses

- Premature fusion of the epiphyses has been reported in pediatric patients exposed to Erivedge. In some cases, fusion progressed after drug discontinuation. Erivedge is not indicated for pediatric patients

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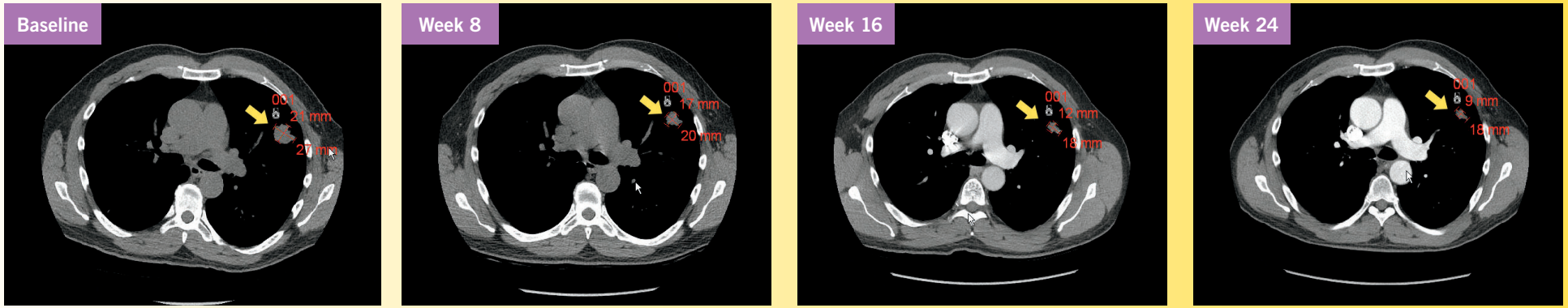
Erivedge® (vismodegib) capsule

Paul, a 56-year-old with metastatic BCC[3]

Left lung: Metastatic BCC



Paul's history of BCC

- Paul was initially diagnosed with BCC in 1995
- He underwent multiple Mohs surgeries and excisions (forehead, nose, cheek, back, and leg)
- Metastasis to the lungs was identified in 2009

Treatment

- Paul started treatment with Erivedge in July 2009 and was treated for 16.4 months
  - In the ERIVANCE trial, the median duration of treatment was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts[1]
- He continued on treatment as of the data cutoff in November 2010

Clinical outcome

- Paul experienced a partial response, as assessed by independent review
  - Partial response is defined as ≥30% decrease in sum of longest diameter of target lesions from baseline

Treatment-related adverse reactions

- Paul experienced abnormal hair growth, acne, alopecia, decreased appetite, dizziness, dysgeusia, epistaxis, fatigue, muscle spasms, and weight loss

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Adverse Reactions

- The most common adverse reactions (≥10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia
- Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown. In clinical trials, 30% of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia (4%), azotemia (2%), and hypokalemia (1%)
- Additionally, in a post-approval clinical trial conducted in 1232 patients with locally advanced or metastatic BCC treated with Erivedge, a subset of 29 patients had baseline values for blood creatine phosphokinase (CPK) reported. Within the subset of patients, 38% had a shift from baseline, including Grade 3 (3%) increased CPK. Grade 3 or 4 increased CPK occurred in 2.4% of the 453 patients across the entire study population with any CPK measurement
- Adverse reactions identified during post-approval use: drug-induced liver injury, Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms

Use in Specific Populations

Lactation

- No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise women that breastfeeding is not recommended during therapy with Erivedge and for 24 months after the final dose

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Erivedge® (vismodegib) capsule

Boxed Warning and Additional Important Safety Information

Boxed Warning

EMBRYO-FETAL TOXICITY

- **Erivedge can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Erivedge is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations**
- **Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge. Advise pregnant women of the potential risks to a fetus. Advise females of reproductive potential to use effective contraception during and after Erivedge**
- **Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential**

- Females of Reproductive Potential: Use contraception during therapy with Erivedge and for 24 months after the final dose
- Males: Use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female partners of reproductive potential during and for 3 months after the final dose of Erivedge. Do not donate semen during and for 3 months after the final dose of Erivedge
- Blood Donation: Advise patients not to donate blood or blood products while receiving Erivedge and for 24 months after the final dose of Erivedge
- Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at (888) 835-2555

Additional Important Safety Information

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during treatment with Erivedge. Permanently discontinue Erivedge in patients with these reactions

Premature Fusion of the Epiphyses

- Premature fusion of the epiphyses has been reported in pediatric patients exposed to Erivedge. In some cases, fusion progressed after drug discontinuation. Erivedge is not indicated for pediatric patients

Adverse Reactions

- The most common adverse reactions (≥10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia
- Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown. In clinical trials, 30% of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia (4%), azotemia (2%), and hypokalemia (1%)
- Additionally, in a post-approval clinical trial conducted in 1232 patients with locally advanced or metastatic BCC treated with Erivedge, a subset of 29 patients had baseline values for blood creatine phosphokinase (CPK) reported. Within the subset of patients, 38% had a shift from baseline, including Grade 3 (3%) increased CPK. Grade 3 or 4 increased CPK occurred in 2.4% of the 453 patients across the entire study population with any CPK measurement
- Adverse reactions identified during post-approval use: drug-induced liver injury, Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms

Use in Specific Populations

Lactation

- No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise women that breastfeeding is not recommended during therapy with Erivedge and for 24 months after the final dose

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

References: 1. Erivedge® (vismodegib) capsule Prescribing Information. Genentech, Inc. July 2020. **2.** Sekulic A, Migden MR, Oro AE, et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. *N Engl J Med*. 2012;366(23):2171-2179. **3.** Data on file. Genentech, Inc. **4.** Common Terminology Criteria for Adverse Events v3.0 (CTCAE). National Cancer Institute. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf. Accessed August 6, 2020.

Do you see patients with advanced BCC in your practice?

Visit Erivedge.com to learn more about Erivedge

Please see full Prescribing Information, including the **BOXED WARNING** and the Medication Guide, for a complete discussion of the risks associated with Erivedge.

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Erivedge® (vismodegib) capsule