

# Investor Call

## January 27, 2023

# Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the benefits we expect to receive under our agreement with Galderma; expected net sales and royalty income in line with volume growth of EPSOLAY and/or TWYNEO; and our expected cash runway. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management’s current expectations and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, the risk that the initiation or results of the Phase 3 study for patidegib will be delayed or not occur, the risk that our annual net sales from patidegib will be lower than expected, the risk that the investment by Mr. Mori Arkin will not be approved by shareholders, , risks that our cash runway will be shorter than expected, risks relating to the effects of COVID-19 (coronavirus) as well as the following factors: (i) the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; (ii) our ability to complete the development of our product candidates; (iii) our ability to find suitable co-development partners; (iv) our ability to obtain and maintain regulatory approvals for our product candidates in our target markets, the potential delay in receiving such regulatory approvals and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; (v) our ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our ability to establish adequate sales, marketing and distribution channels; (ix) acceptance of our product candidates by healthcare professionals and patients; (x) the possibility that we may face third-party claims of intellectual property infringement; (xi) the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products; (xii) intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation in the United States, Europe or Israel; and (xv) loss or retirement of key executives and research scientists. These and other important factors discussed in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”) on April 4, 2022, as amended, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Except as required by law, we undertake no obligation to update any forward-looking statements in this press release

## **SGT-610 (Patidegib Gel, 2%): a Phase-3-Ready NCE Asset for the Prevention of BCCs in Adults with Gorlin Syndrome**

**Recent Acquisition by Sol-Gel**

## Gorlin Syndrome (GS) Patients May Have Thousands of BCCs During Their Lifetime

Painful repeated surgical excision is the standard of care for BCCs until this becomes impossible



Photos by courtesy of Gorlin Syndrome Alliance

# Potential Market Opportunity > \$300M

~17,000 adult Gorlin syndrome patients with BCCs worldwide

US prevalence is 1 in 27,000-31,000 (11,000 individuals) out of which 90% have BCC by the age of 35<sup>†</sup>

EU, UK and CH prevalence is 1 in 40,000-60,000 out of which 67% have BCC<sup>‡</sup>

We estimate 44% to 55% market share and patient treatment adherence of 65%\*

Annual cost of treatment by oral HHIs > \$100,000

<sup>†</sup> Gorlin Syndrome Alliance website, <sup>‡</sup> Spiker AM, StatPearls. Treasure Island (FL): PMID: 286613671; J. Skin Cancer. 2011; 2011: 217378

\* Patient Preference and Adherence 2019;13 2029-2038

# Leo Valued Topical Patidegib at \$760 Million + Double-Digit Royalties

Leo's deal with PellePharm terminated following Phase 3 failure



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## LEO Pharma inks \$760M rare skin disease R&D deal with PellePharm

By **Conor Hale** • Nov 20, 2018 06:00am

**Bloomberg**

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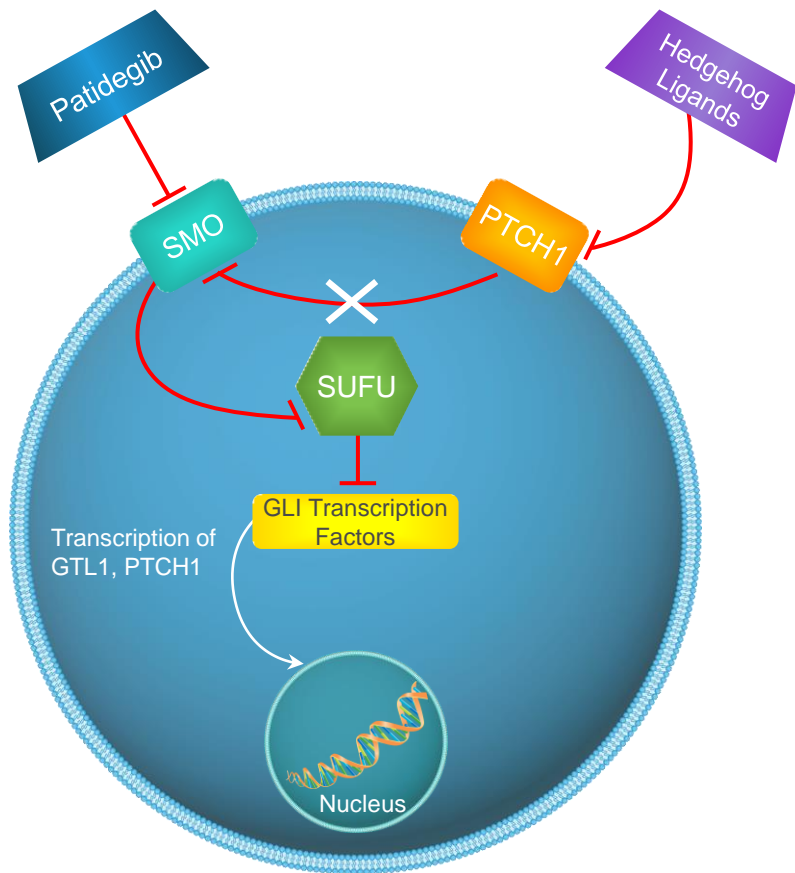
## LEO Pharma and PellePharm Announce \$760 Million Collaboration to Advance Innovative Therapies for Rare Skin Diseases

The PellePharm / Leo deal started with \$70M equity financing and R&D support to fund a global Phase 3 trial

PellePharm was to receive up to additional \$690M upon completion of certain regulatory and commercial milestones, in addition to double-digit royalty payments

# Hedgehog Inhibitors can Remit BCCs in GS, but Adverse Events Result in Discontinuation

GS patients with mutations other than in PTCH1 do not respond to hedgehog inhibitors

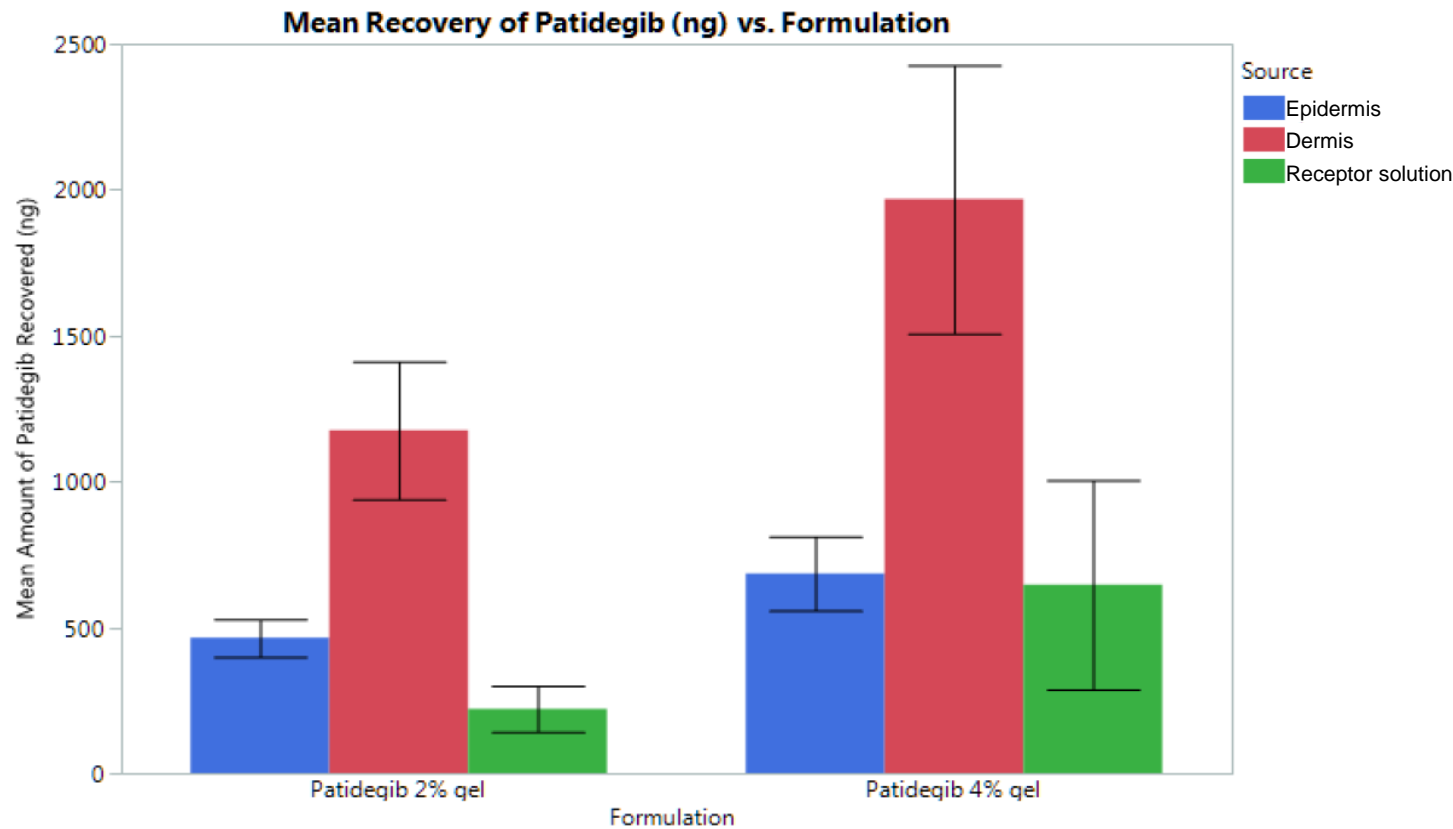


Adverse Reaction	(N = 138)		
	All Grades <sup>1</sup> (%)	Grade 3 (%)	Grade 4 (%)
<b>Gastrointestinal</b>			
Nausea	30%	0.7%	-
Diarrhea	29%	0.7%	-
Constipation	21%	-	-
Vomiting	14%	-	-
<b>General</b>			
Fatigue	40%	5%	0.7%
<b>Investigations</b>			
Weight loss	45%	7%	-
<b>Metabolism and nutrition</b>			
Decreased appetite	25%	2.2%	-
<b>Musculoskeletal and connective tissue</b>			
Muscle spasms	72%	3.6%	-
Arthralgias	16%	0.7%	-
<b>Nervous system</b>			
Dysgeusia	55%	-	-
Ageusia	11%	-	-
<b>Skin and subcutaneous tissue</b>			
Alopecia	64%	-	-

<sup>1</sup> Grading according to National Cancer Institute-Common Terminology Criteria for Adverse Events version 3.0.

# SGT-610 Aims to Prevent New BCCs in GS Without Systemic Adverse Events

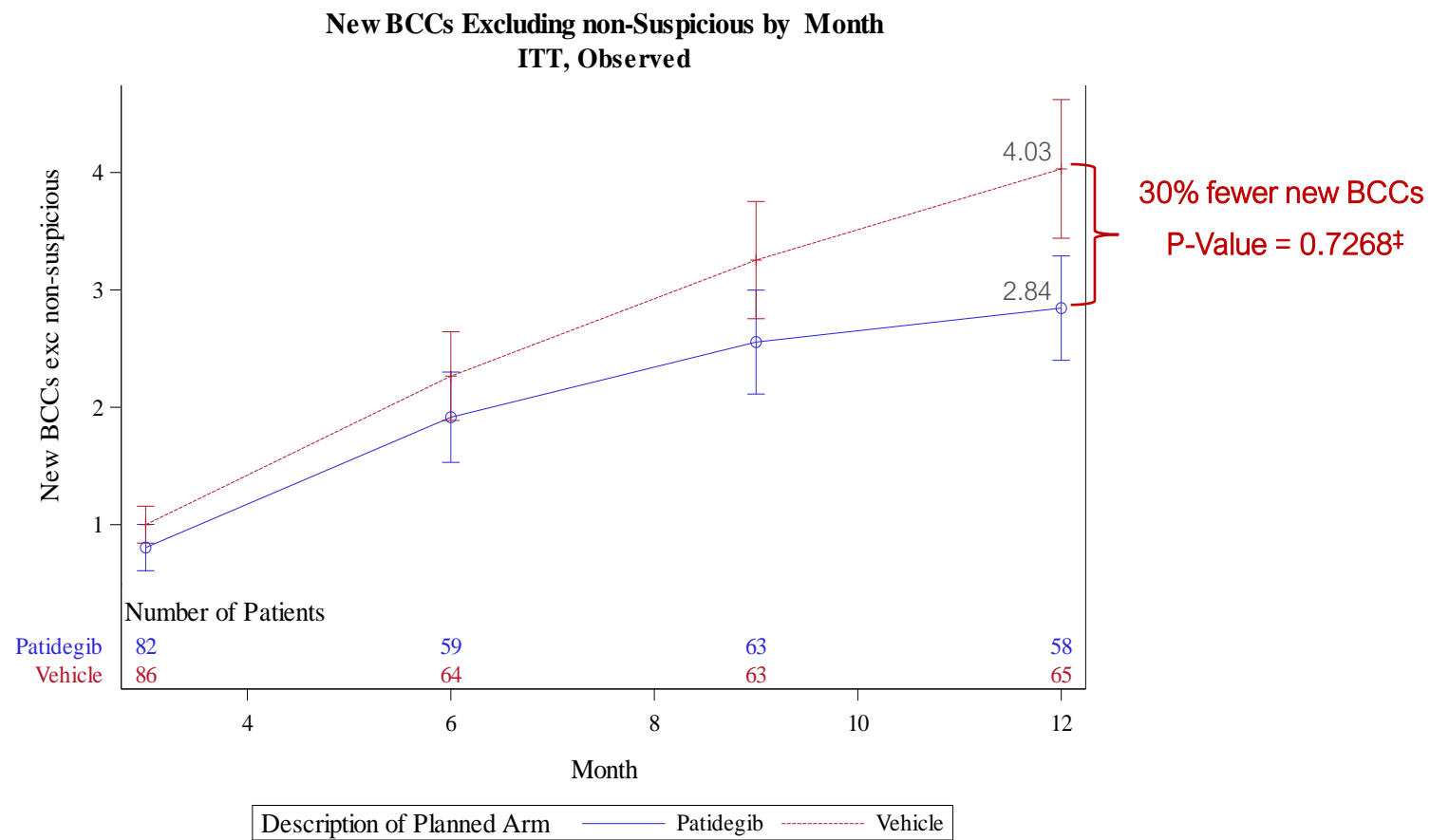
“Orphan Drug” and “Breakthrough Therapy” designations have been granted



Amount of patidegib (ng) recovered from the epidermis, dermis and receptor solution 24h post-application of patidegib 2% and 4% gel formulations. The data is presented as the mean  $\pm$  SEM (n=11-12 across 3 individual skin donors)

# PellePharm Failed in Phase 3 Despite 30% Fewer New BCCs

Subjects were not tested for their GS mutations and subjects with as few as 2 BCCs were enrolled<sup>†</sup>



<sup>†</sup> Pelle-926-301 study design: 12-month, double blind, 1:1 vehicle controlled, entire face, BID, subjects with a minimum of 2 small BCCs at baseline  
<sup>‡</sup> Missing data of subjects who discontinued due to adverse events, use of a prohibited concomitant medication or lack of efficacy were imputed based on vehicle; and imputed based on randomized treatment for remaining subjects

# Influence of Baseline Severity on Efficacy

Post-hoc analysis reveals 48% fewer new BCCs for higher-burden PTCH1 positive patients

Post Hoc Negative Binomial Analysis of the Number of new Basal Cell Carcinomas per Subject by Month 12 using Multiple Imputation by Subgroups – mITT Population†

Variable Subgroup Statistic	Patidegib (N = 52)	Vehicle (N=58)
Baseline BCCs Split by Overall Median		
< = 10.5 BCCs at Baseline	30	26
Total new BCCs	70	55
LS Mean for new BCCs per year (Std Err)	2.93 (0.74)	1.77 (0.51)
95% CI	(1.48, 4.38)	(0.78, 2.77)
Rate-ratio: Patidegib / Vehicle (Std Err)	1.65 (0.39)	
95% CI of Mean Ratio	(0.77, 3.54)	
P-value (1)	0.1958	
>10.5 BCCs at Baseline		
Total new BCCs	47	174
LS Mean for new BCCs per year (Std Err)	3.77 (0.76)	7.24 (1.09)
95% CI	(2.27, 5.26)	(5.11, 9.38)
Rate-ratio: Patidegib / Vehicle (Std Err)	0.52 (0.25)	
95% CI of Mean Ratio	(0.32, 0.85)	
P-value (1)	0.0098	

48% fewer  
new BCCs

†mITT = ITT population showing mutation in PTCH1  
(1) P-values are obtained from a Negative Binomial regression with number of BCCs of BCCs at Baseline as covariate. Subjects who dropped out due to lack of efficacy or adverse events or used a prohibited concomitant medication were imputed based on Vehicle new BCC counts. Other subjects with missing data were imputed by randomized treatment new BCC counts.

# “Explore the Impact of Baseline Disease Characteristics on Outcomes”

FDA’s advice on the design of a new Phase 3 is in line with our findings

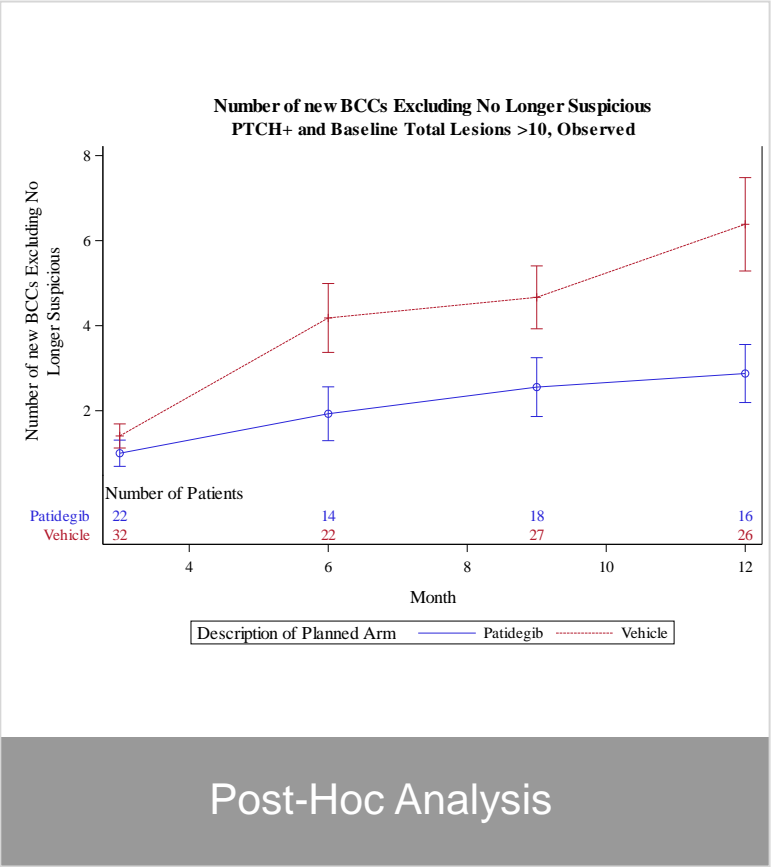
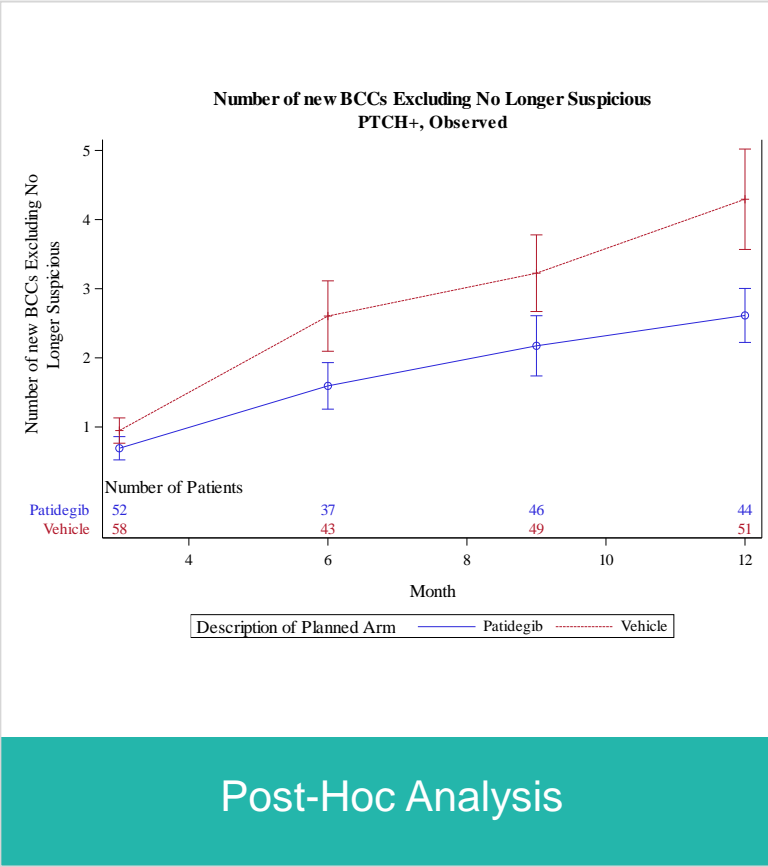
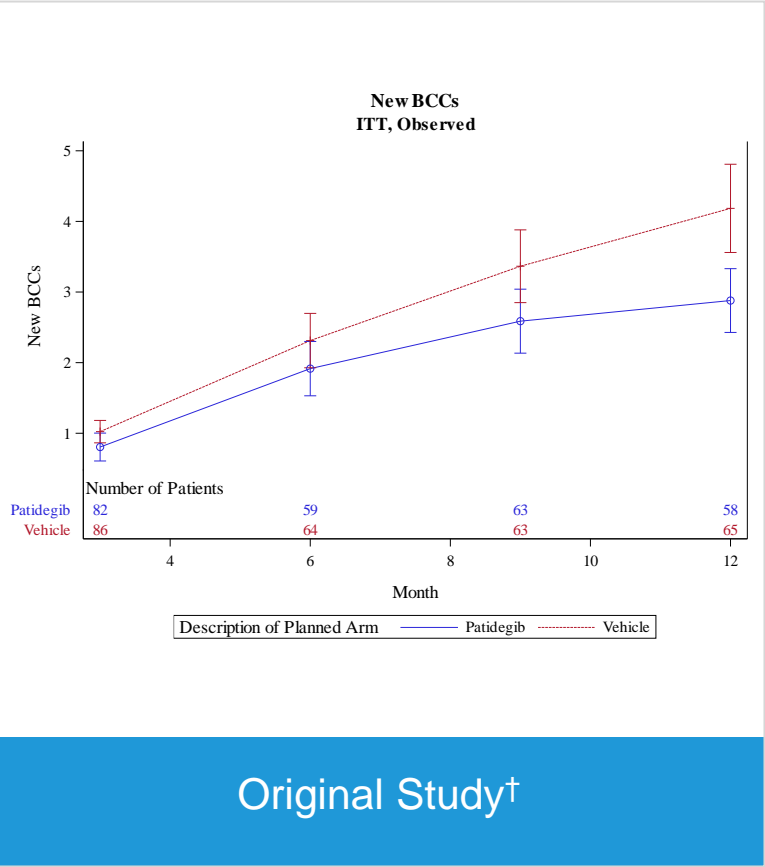
## FDA’s Advice

“We also note that Study Pelle-926-301 had a fairly high proportion of subjects with missing data, and that treatment effect estimates were sensitive to the handling of missing data and adjustments for covariates. It may be useful to explore the impact of baseline disease characteristics on outcomes to assist in identifying appropriate design characteristics and consider ways to improve subject retention in future trials.”

FDA, May 2021

# Early Onset of Action is Expected for PTCH1 Positive and Higher-Burden Patients

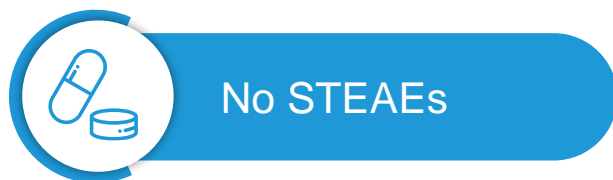
Original vs. post-hoc analyses of PellePharm’s Phase 3 results



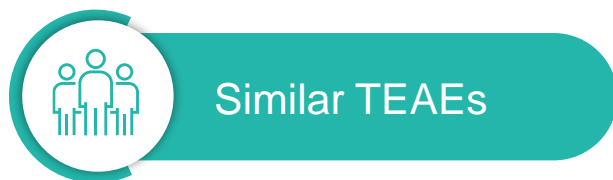
† Pelle-926-301

# No Safety Signal Identified in PellePharm's Phase 3 Study

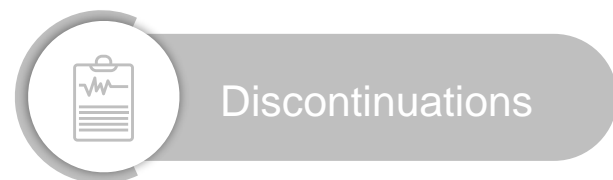
Patidegib gel demonstrated safety and tolerability profiles similar to vehicle



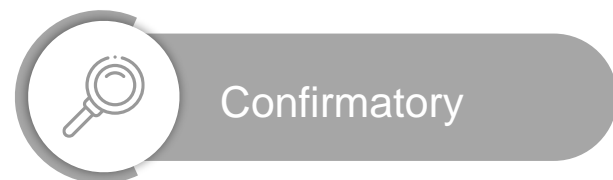
Related Serious Treatment Emergent Adverse Events (STEAEs): None



Related Treatment Emergent Adverse Events (TEAEs): Patidegib – 26 subjects; Vehicle – 28 subjects



Related TEAEs leading to discontinuation: Patidegib – 3 subjects (diarrhea, application site pain, pain); Vehicle – 1 subject (face edema)



These findings are in line with the low plasma distribution of topical patidegib found in *in vivo* studies

# Potential to be the First Therapy for Preventing New BCCs in GS, if Approved

Our upcoming Phase 3 will include necessary adjustments for inclusion criteria



In line with the FDA's advice and the above empirical findings, we intend to:

- (1) Only include GS patients having PTCH1 mutation, which is the most common; GS patients with mutations in SUFU gene will not respond to patidegib as SUFU is downstream of SMO gene
- (2) Only include patients with high baseline lesion burden – as SGT-610 is aimed to be a prophylactic treatment



FDA and EMA have agreed to a single Phase 3 trial



We plan for 100-150 subjects with 90% power

# Payments to PellePharm

Upfront payment  
\$4.7M

Development and  
NDA acceptance  
milestones up to  
\$6M

Commercial  
milestones up to  
\$64M\*

Single Digit  
Royalties\*

\* Higher only if sales exceed \$500M

# Sol-Gel's Products and Pipeline

Adding SGT-610: A Phase-3-Ready Asset



# Summary

- SGT-610, if approved:
  - expected to be the 1<sup>st</sup> therapy for preventing new BCC lesions in Gorlin syndrome patients
  - will have 7/10 years of exclusivity in the US/EU
  - represents an annual net revenue opportunity with the potential to exceed \$300M
- SGT-610 Phase 3 study is expected to be initiated in 2H 2023, with results by end of 2025
- EPSOLAY and TWYNEO have significant market penetration; Favorable agreement with Galderma
- SGT-210 in Pachyonychia Congenita is about to complete Phase 1; Another rare underserved disease
- We anticipate that our cash resources will enable funding until mid-2025

**THANK YOU**