

# Aesthetic Opportunity Within Medical Dermatology

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## The Aclaris Opportunity



#### **COMPANY BACKGROUND**

- Founded in August 2012
- Vicept management team and investors
- Lead indication is the treatment of Seborrheic Keratoses (SKs)
- Additional indication: Verrucae (Warts)

#### PRODUCT PROFILE

- Topical solution/gel
- Mechanism: lipid and membrane peroxidation and apoptosis
- Clinical POC
- Known safety profile

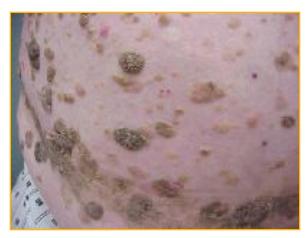
## SIGNIFICANT MARKET OPPORTUNITY

- SK most common benign tumor in older adults
- \$350M annual US market potential
- Multiple distribution channels for commercialization
  - Office-based procedure
  - Take home RX

Opportunity to Formalize the Market and Become the Standard of Care

## Seborrheic Keratosis Background







## SEBORRHEIC KERATOSES ARE THE MOST COMMON BENIGN TUMOR IN OLDER INDIVIDUALS

- Proliferation of Epidermal Cells
  - Etiology and pathogenesis unclear
  - Hyper-adherent senescent cells exhibiting decreased apoptotic cell death
  - Ultrastructurally Abnormal intercellular structures with dense plaques between keratinized cells
- Lesions arise in young and old
  - 70-100% adults > 50 years
  - 8-38% adults <40 years</li>
- Current treatment options
  - No treatment
  - Liquid nitrogen cryotherapy
  - Surgical removal
  - Laser

First Topical Treatment of Seborrheic Keratosis (SK)

## Unmet Need Current therapeutic options have significant limitations



## **Limitations on Efficacy / Outcomes**

Dyspigmentation or scarring

## **Procedure Feasibility**

- Painful
- Treatment of numerous lesions is impractical

## **Variability of Technique**

Cryotherapy uncontrolled and highly variable

## **Physician Resource Intensive**

 Current procedures must be done by physician





## A-101: First topical SK treatment Treat a Cosmetic Condition with an Aesthetic Solution



### **Efficacy**

- Demonstrated efficacy in controlled study
- Improved cosmetic benefit (No dyspigmentation or scarring)

### **Procedure Impact**

- Minimal pain
- Ability to treat larger numbers of lesions

## **Standardized Technique**

 Consistent results across patients – less dependent on physician technique

### **Simplicity of Therapy**

Ability to hand off to ancillary staff



## **Demonstrated Efficacy in POC Studies**



#### **FEMALE: FULL CLEARANCE**



**Before Treatment** 



**After Treatment** 

#### MALE: FULL CLEARANCE







After Treatment

#### SAFE TO USE IN SENSITIVE PERIORBITAL REGION



**Before Treatment** 



After 8 Days

## Market Opportunity SK in Top 5 Dermatology Diagnoses



## PREVALENCE AND DIRECT, INDIRECT AND TANGIBLE COSTS OF SELECTED SKIN DISEASES, U.S.

DISEASE	PREVALENCE <sup>†</sup> (MILLIONS)	DIRECT COST§ (\$ BILLIONS)	INDIRECT COST DUE TO LOST PRODUCTIVITY (\$ BILLIONS)	TOTAL DIRECT AND INDIRECT COST** (\$ BILLIONS)	INTANGIBLE COST DUE TO QOL IMPACT (\$ BILLIONS)
Herpes Simplex/ Herpes Zoster	165.0	\$1.7	\$0.3	\$2.0	\$1.4
Solar Radiation Damage	123.1	\$0.4	\$0.03	\$0.4	\$1.0
Seborrheic Keratosis	83.8	\$1.1B	\$0.1B	\$1.2B	\$6.7B
Contact Dermatitis	72.3	\$1.6	\$0.62	\$2.2	\$1.9
Acne (Cystic and Vulgaris)	50.2	\$2.5	\$0.6	\$3.2	\$12.0

<sup>†</sup> Prevalence estimates are drawn from multiple data sources, all of which are adjusted to 2004 equivalents.

<sup>§</sup> Estimates based on 2002-2003 National Ambulatory Medical Care Survey, 2002-2003 National Hospital Ambulatory Medical Care Survey, 2001 Medicare Standard Analytic File, 2003 Scott-Levin Source Prescription Audit, and AC Nielsen OTC Data.

<sup>¥</sup> OTC costs not attributable to a particular condition, with the exception of acne, psoriasis, jock itch, sunburn, hair growth products.

<sup>\*</sup> Inflated to 2004 dollars using Medical CPI.

<sup>\*\*</sup> Indirect cost estimates include only lost days of work due to consumption of health care. Estimates based on other studies in the literature are noted throughout this report.

## **Development Summary**



## **Pre-Clinical/Formulation/CMC - Completed**

- 6 Month Accelerated Stability Testing of Solution
- 3 Month Accelerated Stability Testing of Gel Formulation
- IND-enabling preclinical toxicology: rat and minipig

## Phase I/II - Underway

 Single-center, randomized, double-blind, vehicle-controlled, within subject comparison study of the safety, tolerability and effectiveness of A-101 topical solution in subjects with Seborrheic keratosis

### **Phase IIb - Planned**

- Randomized, double-blind, placebo-controlled, multi-center dose-ranging study
- EOPII meeting anticipated in 2H 2014

## **Summary of Opportunity**



## SIGNIFICANT UNMET NEED

- Prevalence Rates
   Over 60% that
   Increase with Age
- Patients and
  Clinicians Seeking
  New Options for
  Safer and more
  Elegant Treatment

### RISK REDUCED ASSETS

- Well known active with long track record of safety
- Clinical POC
   Demonstrated

### CLEAR CLINICAL PATH FORWARD

- Regulatory
   Precedents Exist
- Acute Treatment with Shorter Trial Duration

## COMPELLING COMMERCIAL OPPORTUNITY

- 2x as many SK procedures as Botox procedures on average
- \$350 MM/Year
   US Market
   Opportunity
- Additional Upside:
  - Take-Home Rx
  - Ex-US
  - Wart indication