Creating Innovation in Dermatology

Investora

Zürich, 21. September, 2016

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Cassiopea Übersicht

- IPO 7/2015 war grösster healthcare IPO an der SIX seit 2000
  - 10 Millionen ausgegebene Aktien, Sekundärplazierung von 5.18 Millionen Aktien die Cosmo hielt; Cosmo Pharmaceuticals NV hält weiterhin 45.1%
- Ausschliesslicher Fokus auf Dermatologie
- Innovative fortgeschrittene Pipeline von 4 Produkten die alle eine NCE enthalten
- Erfahrenes Management team und tiefe Kosten während der Produktentwicklungsphase
- Infrastruktur und Dienstleistungen werden von Cosmo Pharmaceuticals zu arms' length Bedingungen geliefert
- Strategie:
  - Finanzierung sichergestellt bis zur Publikation der Winlevi Phase III Resultate
  - Integrierte Organisation erst nach Bewilligung von Winlevi® in USA vorgesehen. Partnerschaften für RdW erst vorgesehen nach Vorlage der Winlevi Phase 3 Daten

Übersicht der Entwicklungsprojekte Cassiopea

Produkt	Pre-Klinik	Phase I	Phase II	Phase III	MA / Erwartete Lancierung	Nächster Katalyst
Winlevi® ACNE Anti-androgen **NCE**(1)				H2 2017	2018/19	H2 2017 (Ph 3 data)
Breezula® ALOPECIA Anti-androgen **NCE**(1)			POC completed H1 2016 DR H1 2018	2019-20	2021	H1 2018 (Ph II DR data)
CB-06-01 ACNE Antibiotic **NCE**			POC H2 2016 DR 2018	2019-20	2021	H2 2016 (POC)
CB-06-02 HPV Integrin activator **NCE**			POC H1/H2 2017 DR 2019	2020-21	2022	H1 2017 (POC)

POC = Proof of Concept
DR = Dose Ranging

(1) Winlevi® and Breezula® are different formulations of the same NCE, for different indications.

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Winlevi® Laufendes Phase III Program

Phase III Program und Versuchsreihe

- Special Protocol Assessment (SPA) von FDA bewilligt im Juli 2015
- Winlevi® 1% cream zwei mal täglich aufgetragen für 12 Wochen in Subjekts mit Gesichstakne
- FDA verlangt mindestes 1,000 behandleete Subjekte zur Sicherheitsevaluation (NCE)
- 2 pivotale Versuchsreihen (Standorte sowohl in USA und EU) mit je 700 Subjekten
  - ESE November 2015 / LSE in Q4 2017
  - Aufnahme von Subjekten mit 9 Jahren und älter mit moderater bis schwerer Akne (Stufe 3 und 4 auf dem IGA)
  - Daten sollten verfügbar sein Q4 2017/Q1 2018
- 1 langfrist open label Sicherhietsversuchreihe: 300+ Subjekte 6 Mte, 100 Subjekte 12 Mte Aussetzung
- NDA filing geplant mitte 2018

Studien Endpunkte

Primär

- Anteil der Subjekte mit IGA Resultat von 0 (frei) oder 1 (fast frei) und einer mindest Reduktion von zwei Pkten in IGA im Vergleich zur Ausgangslage
- Absolute Änderung gegenüber Ausganglage in der Anzahl nicht entzündlicher Läsionen zur Woche 12
- Absolute Änderung gegenüber Ausganglage in der Anzahl entzündlicher Läsionen zur Woche 12

Sekundär

- Absolute und % Änderung ab Ausganglage der Gesamtzahl der Läsionen zur Woche 12
- %ualer Wechsel gegenüber Ausgangslage in nicht entzündlichen Läsionen zur Woche 12
- %ualer Wechsel gegenüber Ausgangslage in entzündlichen Läsionen zur Woche 12

IGA = Investigator Global Assessment.

Phase 3 Akne Studien

42% enrolled

Studie 25 US (per 7 Sept 16)

- Alle 36 Standorte aktiviert
- 271 randomisierte Subjekte
- 109 abgeschlossen

Studie 26 EU (per 7 September)

- 37 Standorte rekrutieren aktiv (26 EU Standorte, 11 US Standorte)
- 344 randomisierte subjekte
- 185 abgeschlossen

Studie 27 EU/US Open Label Lanfristige Sicherheitsstudie

- 154 Subjects sind aus den Studien 25 und 26 übergetreten
  - 48 aus der Studie 25
  - 96 aus der Studie 26

PoC Konklusionen & nächste Schritte

Haarwachstums Beurteilung (HGA)

- Sowohl Breezula und Minoxidil Subjekte hatten eine Erhöhung des HGA Resultates
  - Breezula 39.1%
  - Minoxidil 36%
- Die Resultate pro Subjekte korrelieren mit den Haarzählungsresultaten für alle Behandlungsgruppen
- Das HGA Profil der behandelten Subjekte ist sehr ähnlich dem das bei anderen Produkten observiert werden konnte i.e. Minoxidil, finasteride
- Gesamthaft zeigen die Resultate der POC Studie ein günstiges Effizienzprofil von CB-03-01 5% mit dem Potenzial höherer und andauernder Wirksamkeit ohne die systemischen Effekte von oralem finasteride

Lokale Tolerabilität und Sicherheitsprofil

- Lokale Hautreaktionen die am Anfang und während der Behandlung observiert wurden waren minimal und nahmen über die Zeit ab
- Keine signifikanten systemischen AEs (unerwünschte Ereignisse)

Phase II Dosierung Evaluations Studie startet in 4Q 2016

Dosierungsstudie

- Phase 2, multizenter, prospektiv, randomisiert, Vehikel kontolliert
- Dosierungen von 2,5%; 5%; 7,5% BID und 7,5% QD und Vehikel
- 6 Zentren in Deutschland; 400 Subjekte, männlich, 18-55 Jahre
- ESE Q1 2017; 12 Monate Behandlungszeit; Interimanalyse nach 6 Monaten

CB-06-01 NAI Acne

- Topisches Antibiotikum zur von Akne; behindert die bakterielle Proteinsynthese
- Einlizensiert
- 90 Subjekte in der Slovakei, 12 Wochen Behandlung mit 3% Gel
- Absolute und %uale Änderung der entzündeten Läsionen
- Go-No Go Q3/Q4 2016 abstellend auf den POC Resultaten
- Re-Formulierungs- und Hautpenetrationsstudien nach den POC Resultaten
- Produktsyntheseoptimierung und Toxizitätsstudien nötig bevor das IND in 2017 eingereicht werden kann

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CB-06-02 AS-101-Genitalwarzen

- Auf Tellurium abstellendes topisches Produkt zur Behandlung von Genitalwarzen
- Wirkt als anti viraler Agent gegen Warzen an der Hautoberfläche
- Doppel-blind randomisierte Studie mit 15% Gel/Placebo QD für bis zu 14 Wochen oder kompletter Beseitigung, durchgeführt in Israel
- 30/60 Subjekte sind bisher rekrutiert worden
- Lizenzgeber ist stillgelegt worden; Cassiopea hat Kontrolle der Studie übernommen.
- Resultate H1 2017 erwartet

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Meilensteine

2016

- H2 PoC data CB-06-01 Acne antibiotic
- H2 Breezula PH2 DR Studie beginnt

2017

- H2 PoC data CB-06-02 HPV
- H2 EvPIII Winlevi®
- H2 Winlevi Phase 3 results & Pre - NDA meeting

2018

- H1 NDA filing Winlevi®
- H2 Breezula Phase 2 DR Resultate

Note: Current timing is based on certain assumptions with regards to progression through clinical trials and may be subject to delays.

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Cassiopea SpA

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