PledPharma

Annual General Meeting
23rd of April, 2020

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Agenda

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1. Summary and reflections 2019

2. Q1 and year to date 2020

ÅRET I KORTHET

2019

Stort vetenskapligt intresse för Aladote® med presentation vid den globala vetenskapliga konferensen EASL ILC samt publikation av resultaten från fas Ib/IIa-studien i Lancets EBioMedicine. I mars beviljades även särläkemedelsstatus av FDA.

PledPharma och Solasia ingick ett andra licensavtal kring läkemedelskandidaten PledOx® i delar av Asien som täcker cellgiftsinducerad perifer neuropati (CIPN) orsakad av alla kemoterapier.

I oktober 2019 inleddes handel med PledPharmas aktier på Nasdaq OMX Stockholm

Fas III-studien POLAR-A med PledOx®, avsedd för förebyggande av nervskador i samband med cellgiftsterapi, blev färdigrekryterat i december.

2020

Övriga händelser för PledOx® och Aladote® under året som gått

2019

Q1

- PledPharma erhöll 600 MJPY, cirka 49 MSEK, i samband med inklusion av den första asiatiska patienten i det globala fas III programmet för PledOx®.

- Aladote® har beviljats särläkemedelsstatus av amerikanska FDA
- POP studiens resultat presenterades på den globala toxikologikonferensen "58th Annual Meeting of the Society of Toxicology" i USA

Q2

- PledPharma presenterade fas III-programmet för PledOx® på den globala cancerkonferensen American Society of Clinical Oncology (ASCO)

- Resultat från POP-studien uppmärksammades som en av höjdpunkterna på en av världens största leverkonferenser European Association of the Study of the Liver International Liver Congress (EASL ILC)

Q3

- Den oberoende expertpanelen DSMB (Data and Safety Monitoring Board) höll sitt första möte och rekommenderade att programmet skulle fortgå utan modifikation.

- Resultaten från proof of principle-studien med Aladote publicerades i the Lancets EBioMedicine, en av de mest välrenommerade facktidskrifterna inom biomedicinsk forskning.

Q4

- Fas III-studien POLAR-A fullrekryterad
- PledPharma och Solasia ingick ett andra licensavtal för utveckling och kommersialisering av PledOx® i Asien, med inriktning på neuropati orsakad av taxaner och alla andra kemoterapier

- Regulatoriska möten med den amerikanska läkemedelsmyndigheten Food and Drug Administration (FDA) och European Medicines Agency (EMA) för rådgivning och diskussion om Aladotes utvecklingsprogram och väg till marknadsgodkännande har hållits

2020

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1. Summary and reflections 2019

2. Q1 and year to date 2020

Q1 and year to date in brief

- January 8, following interactions with the FDA and EMA finalised the development program for Aladote. The development program consists of one pivotal Phase II/III study which is expected to be sufficient for a marketing authorisation application in both US and EU
- January 23, announced that the US Food and Drug Administration (FDA) has issued a clinical hold in the US of the phase III POLAR program for the lead candidate PledOx®. Recruitment and dosing of patients in the POLAR-M study is halted in the US. The POLAR program and both studies will continue as planned in Europe and Asia.
- March 1, announced the decision to place dosing of patients in the pivotal clinical phase III POLAR program for the lead candidate PledOx® on hold. The decision follows interactions with the French regulatory authority, ANSM, and the previously communicated clinical hold issued by the FDA.
- Apr 6, announced that the company has decided to close its pivotal phase III program POLAR with lead candidate PledOx®, with a data cut-off targeted for the third quarter. The totality of data generated will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx.
- Apr 23, Interim report for the first quarter published

POLAR program update

- The POLAR program for PledOx consists of two double-blind, randomized, placebo-controlled pivotal phase III studies, POLAR-A and POLAR-M.
    - Initiated in the end of 2018 with the ambition to randomize a total of 700 pts
- Decision to close POLAR program
    - Recommendation from the independent Drug Safety Monitoring Board (DSMB) to stop the program due to severe allergic reactions – which has been observed in the studies after repeated dosing with study drug
- Patients currently enrolled will continue with their scheduled study procedures targeting a data cut-off by third quarter this year.
- The totality of data generated will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx to evaluate if further activities to find a path forward for PledOx to treat nerve damage associated with chemotherapy is motivated.

Allergic-hypersensitivity reactions

- The safety of patients in our clinical studies is our most important responsibility
- Allergic-hypersensitivity reactions are not uncommon in relation to platinum-based chemotherapy, but the DSMB recommendation to stop the POLAR studies implies that such risk is increased with PledOx
- About the observed events:
    1. No reason to believe that patients previously treated with study drug is currently at risk
    2. All of these severe events were transient and resolved after treatment
    3. All events occurred during the administration of oxaliplatin or study drug.
    4. All events occurred after repeated dosing of study drug. There has been no severe event observed before the 6th cycle of dosing.
- Work ongoing together with external immunology experts to better understand why these allergic-hypersensitivity reactions occur

POLAR program: Current status & next steps

- The totality of data generated in the POLAR program will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx
  - A total of 590 patients out of the planned 700 patients have been randomized
  - Majority of patients are expected to have a sufficient treatment effect of PledOx despite the stop of dosing
    - 420 patients have completed more than 6 cycles of treatment with study drug and about 250 more than 9 cycles
  - Data cut-off by third quarter selected so all patients eligible for 6 cycles of treatment with study drug have completed the 9-month data collection of the primary endpoint
- Data will be collected remotely according to regulatory guidelines during the challenging COVID-19 pandemic

Aladote and Financial situation

- The focus on Aladote with the forthcoming regulatory interactions and its one pivotal Phase II/III study for marketing authorisation application in both US and EU remains
- Aladote for reducing liver damage caused by paracetamol poisoning is not affected by the DSMB recommendation and the early closure of the PledOx POLAR program
    - Single administration
    - There has been no severe event observed before the 6th cycle of dosing in the POLAR program.
- We have a robust cash position with 221 MSEK at end of Q1 2020

Summary

- POLAR program to be closed with a data cut-off targeted for the third quarter this year
- Generation of data will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx to determine the future for PledOx
- Aladote, administered as single dose after which severe allergic reactions have not been observed, is not affected by the DSMB recommendation and the early closure of the POLAR program. The focus on Aladote and the forthcoming regulatory interactions and clinical study remains
- We have a robust cash position with with 221 MSEK at end of Q1 2020

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