



InDex Pharmaceuticals Capital Markets Day

March 14, 2022

Agenda and Presenters for the Day



Introduction to InDex, cobitolimod's market potential and strategy for commercialization Peter Zerhouni, CEO



Planning for commercialisation of cobitolimod in the US Dan Lundberg, External advisor

Break



Cobitolimod and the phase III study CONCLUDE Thomas Knittel, CMO



CONCLUDE executionPernilla Sandwall, COO and Anders Bröijersen, Senior Medical Director

Questions and Answers

All speakers (send questions via the chat function)



Moderator Thilo Bayrhoffer, External advisor







Introduction to InDex Pharmaceuticals

Peter Zerhouni, CEO

Forward Looking Statement

This presentation contains certain forward-looking statements reflecting the Company's current view of future events and financial and operational performance. Such forward-looking statements are associated with both known and unknown risks and circumstances outside the Company's control. All statements in this presentation other than statements of historical or current facts or circumstances are forward-looking statements. Forward-looking statements are made in several sections of the presentation and can be identified by the use of terms or expressions such as "may", "could", "should", "anticipated", "estimated", "expected", "likely", "forecasted", "plans to", "aims to", or conjugations of such terms or similar terms. The forward-looking statements only apply as of the date of this presentation. The Company has no intent or obligation to publish updated forward-looking statements or any other information contained in this presentation based on new information, future events etc. other than required by applicable law, regulation or regulatory framework.





We want to give Felicia and other patients with ulcerative colitis the chance to live a normal life



InDex Pharmaceuticals in Brief

- Cobitolimod for ulcerative colitis in phase III
- Broad portfolio of pre-clinical stage assets from DIMS platform
 - DNA based ImmunoModulatory Sequences
 - Potential in inflammatory diseases



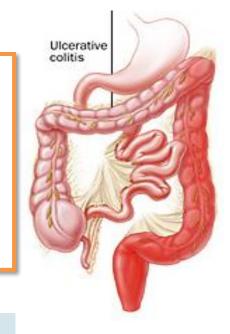
Cobitolimod

- Based in Stockholm, Sweden with origins from Karolinska Institutet
- Listed on the Nasdaq First North Growth Market Stockholm (ticker INDEX)
- Main shareholders: Linc, HBM, 4th AP Fund, Handelsbanken



Ulcerative Colitis – a Debilitating Lifelong Disease

- Chronic inflammation of the colonic mucosa leading to ulcers
- Recurrent with active and inactive periods
- Very frequent blood- and mucus-mixed loose stools
- High negative impact on quality of life



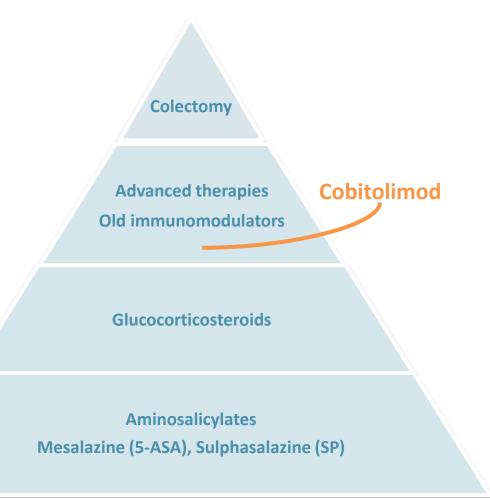


"The worst thing about having ulcerative colitis is probably not knowing. The flares, i.e. when you are ill, can come at any time. I can feel great today and my stomach is behaving normally, but tomorrow I can wake up and have a lot of pain in my stomach and have to go to the toilet several times per hour. That's probably what consumes me the most."

Felicia 23 years old suffering from ulcerative colitis



Enduring High Medical Need For New Therapies in UC



Shortcomings of current advanced therapies



Only have effect on a small fraction of patients



Can cause serious side effects



Act on the whole body, not only the colon



Market leaders are given as injections



Cobitolimod Addresses the Medical Need in UC

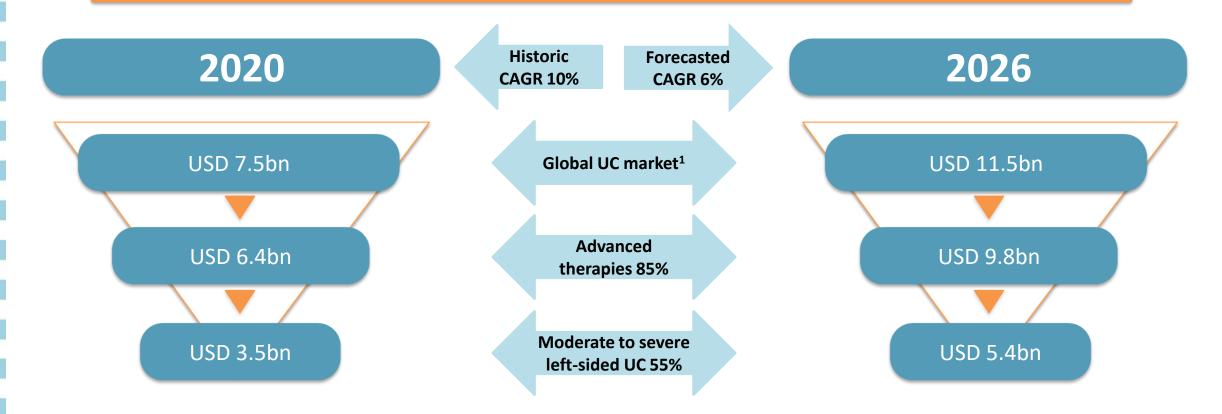
- The only advanced drug candidate specifically targeting moderate to severe left-sided ulcerative colitis
- Phase III study CONCLUDE ongoing
- Primary endpoint met in phase IIb study with an excellent safety profile
- 4 previous completed clinical studies support efficacy and safety demonstrated in phase IIb
- Competitive efficacy
- No known side effects
- Targets the colon
- Infrequent dosing at home
- Novel mechanism of action





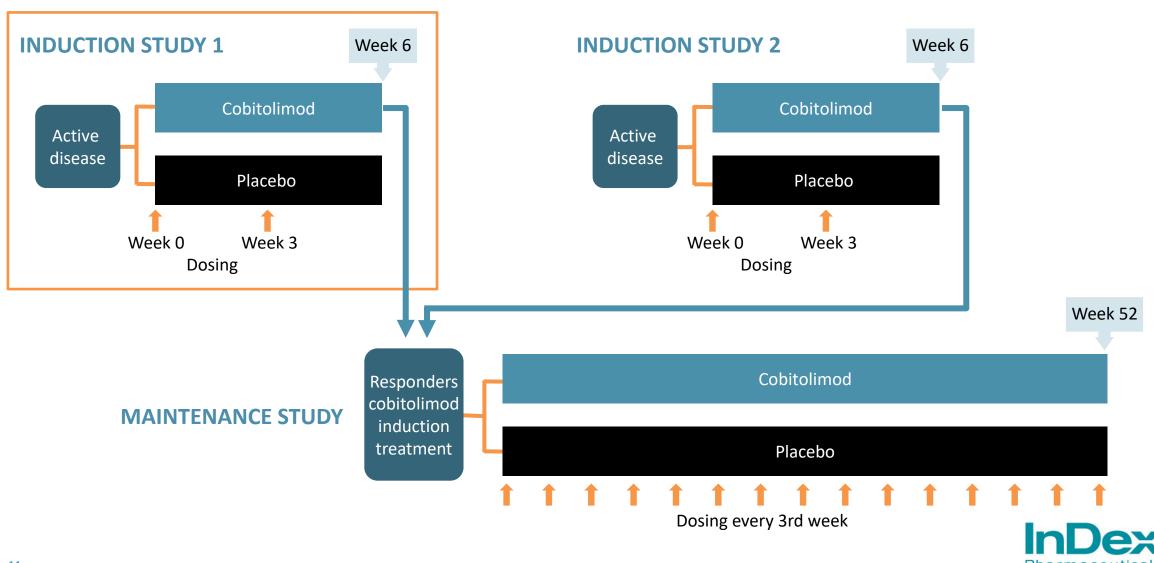
Cobitolimod has Blockbuster Potential

USD +1bn in estimated peak annual sales with a market share of 20-30% in moderate to severe left-sided UC





Cobitolimod Phase III Program for Left-Sided Ulcerative Colitis



Timetable to launch

Results	from first	phase III s	study expected	H2 2023
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 Completion 	of phase III	program and filing	expected 2026
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Marketing approval and launch expected

2027

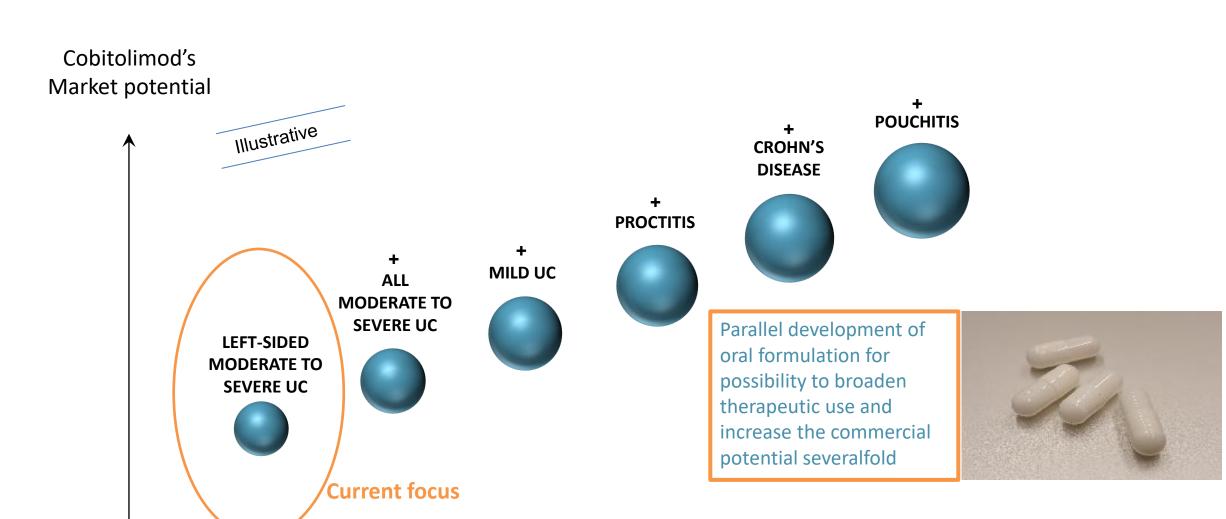


Preparing for Commercialisation of Cobitolimod

- Commercialisation options analysed with external experts in the US and Europe
- Planning for self-commercialisation in the US with expected launch in 2027
 - Attractive business case for a focused commercial organisation to be built closer to launch
- Other regions offer attractive opportunities to enter strategic collaborations as cobitolimod advances towards launch



Significant Market Expansion Possibilities





→ Indications

Investment Opportunity



ADDRESSING MAJOR PATIENT SUFFERING AND ECONOMIC BURDEN OF UC

- Ulcerative colitis is a severe chronic disease that affects people of working age
- The disease causes extensive direct and indirect costs to society



BLOCKBUSTER POTENTIAL

- There is a high unmet medical need for new treatment options for ulcerative colitis
- Cobitolimod has blockbuster potential with an outstanding combination of efficacy and safety and a novel mechanism of action



COBITOLIMOD IN PHASE III

- Financing secured until next pivotal read-out of clinical data
- Preparing for commercialisation







Planning for Commercialisation of Cobitolimod in the US

Dan Lundberg, External Advisor

Project Leadership with Extensive Experience from Commercialisation in the US

Daniel P. Lundberg



- Thilo H. Bayrhoffer

- Active in the US and global pharmaceutical industry for over 30 years
- Of which past 20 years focused on the gastrointestinal ('GI') market
- Chief Marketing Officer, Vivelix Pharmaceuticals Inc.
- Senior Vice President of Marketing, Salix Pharmaceuticals Inc.
- Expert consultant to GI companies globally
 - Over 13 product launches
 - Development, expansion and leveraging of Salix's digital marketing and social media footprint
 - Multiple licensing/co-promotion agreements
 - Planning for- and being accountable for commercial models and P&Ls

- Advisor to biotech and pharmaceutical companies for over 20 years
- Boston Consulting Group, IQVIA*, Syneos Health*, and other leading analytics & research organizations
- Interim C-level executive and non-executive roles
- Co-founder of EmPartners, a strategic consultancy providing commercial excellence, CI, and BD support in the US and Europe
 - Embedded strategic consultants for several years at midsize pharma companies
 - Salesforce sizing & structuring work in multiple indications
 - Pre-launch planning for >40 products
 - Strategic 'stand-alone' or partner commercial model decisions

Commercial Opportunity – Key Takeaways

- Already well established and growing UC market in the US
- UC patients play a prominent role in the management of their disease
- Despite new approvals there is still a significant unmet medical need in UC
- Prescribing physician audience is highly concentrated



US Represents 2/3 of UC Market with USD 5Bn in Sales and Promise of Further Growth

- The US accounts for 65% of total UC market with USD 5Bn of sales in 2020¹
- Annual growth rate of 10% in the past 4 years¹
- Growth driven by increased diagnosis rates, introduction of new therapies, and increased use of advanced therapies in patients with moderate to severe disease
- Promising outlook with projected annual growth rate of 5%-7%¹



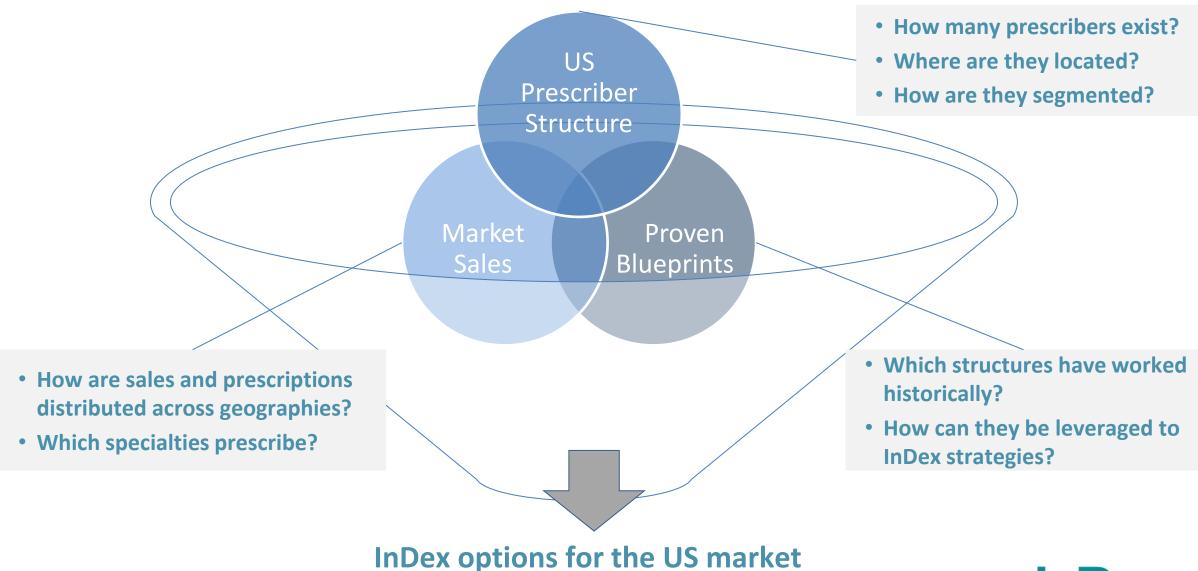
Planning for Commercialisation of Cobitolimod in the US

Key areas considered:

- Which commercial models are employed in the US market?
- How do they match market needs and prescriber structure?
- What are the options for InDex?
- What is the required infrastructure and timing?



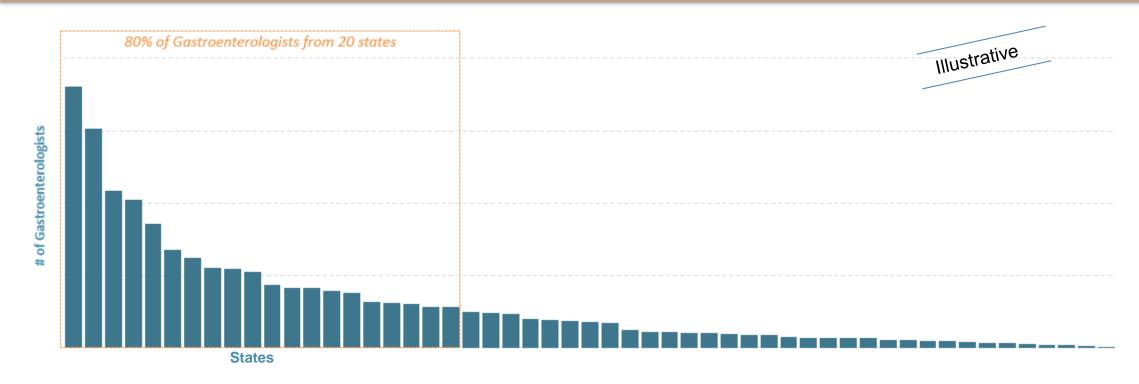
Three Key Analytical Areas in Development of Strategy





Geographic Concentration of Gastroenterologists in the US Offers Opportunity for Focused Commercial Effort

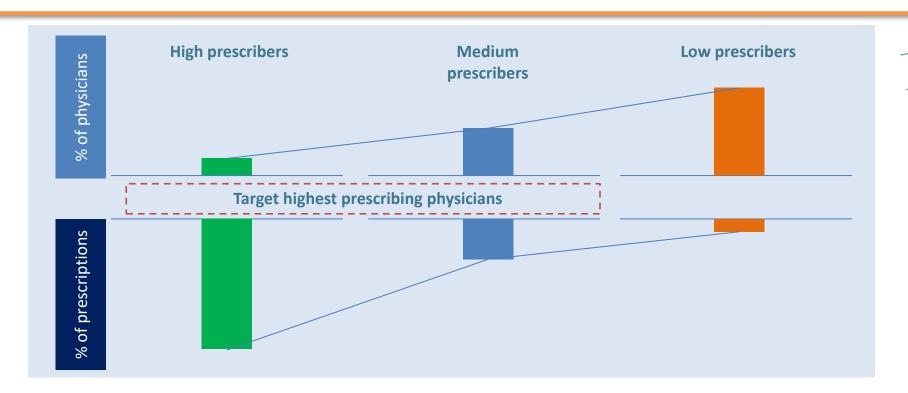
- Less than half of the US states are home to over 80% of accredited Gastroenterologists
- Granular analysis of relevant regions; typically considering zip-code level distribution to define sales areas





Small Proportion of Physicians are High Prescribers Providing a Well Defined Target Universe

- Identification of top volume prescribers show well defined target universe for InDex salesforce
- Model for high-touch interactions and productivity



Illustrative

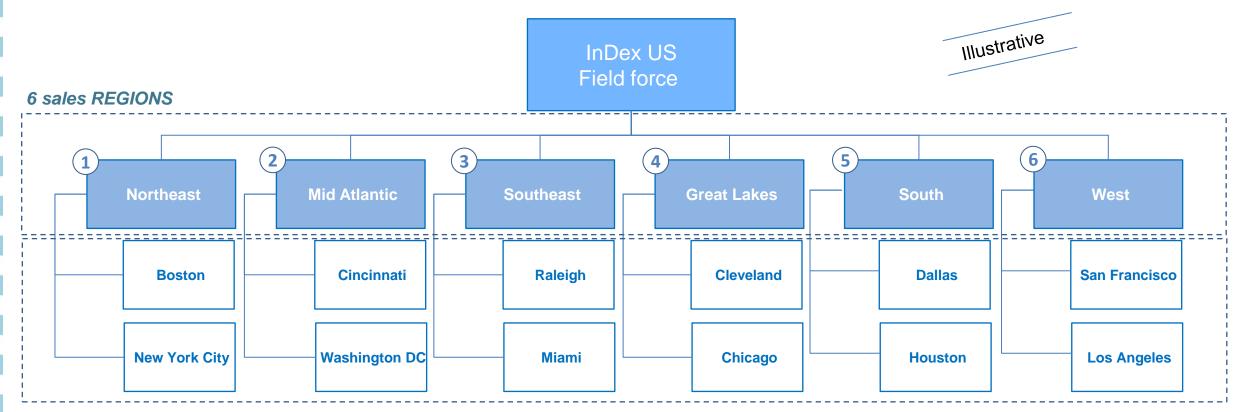


Several Examples of Successful US GI Specialty Launches Support InDex Model

- Analysis of other companies' models for 'single-product' US market entry & launch provide information as analogue case studies on anticipated structures and costs
- Key messages from these analyses are:
 - Concentrated group of prescribers allow for smaller sales force leading to efficient targeting
 - Key to then be able to compete effectively with differentiated product
 - Focus on parameters such as a competent team, capabilities, and patient/physician centricity
 - Narrative for US commercialization of cobitolimod without TV ads and large pharma resources



Cobitolimod can be Successfully Commercialised in the US with a Focused Team of ~100 People







Main Conclusions

- US launch of cobitolimod by InDex is a highly attractive strategy
- Gated investment as clinical milestones are met, with most resources added post 2025
- Aim to build an agile, modern commercial model focused on the UC patient and their physicians
- High geographical concentration of US gastroenterologists
- Small proportion of physicians account for most of the prescriptions for advanced UC therapies
- Several successful examples of focused commercialisation models targeting high prescribing specialists located in selected geographies







Cobitolimod and the Phase III Study CONCLUDE

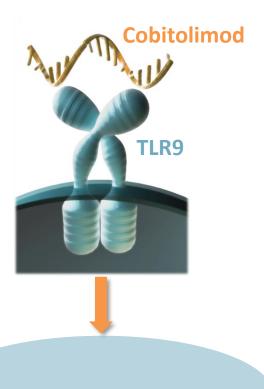
Thomas Knittel, CMO

Cobitolimod is a First-in-Class TLR9 Agonist

Cobitolimod is an oligonucleotide which activates Toll Like Receptor 9 (TLR9) by mimicking microbial DNA

Advantages with novel and unique MoA:

- No competition for the specific MoA
- Address patients that have failed other MoA
- Potential combination therapy with other MoA

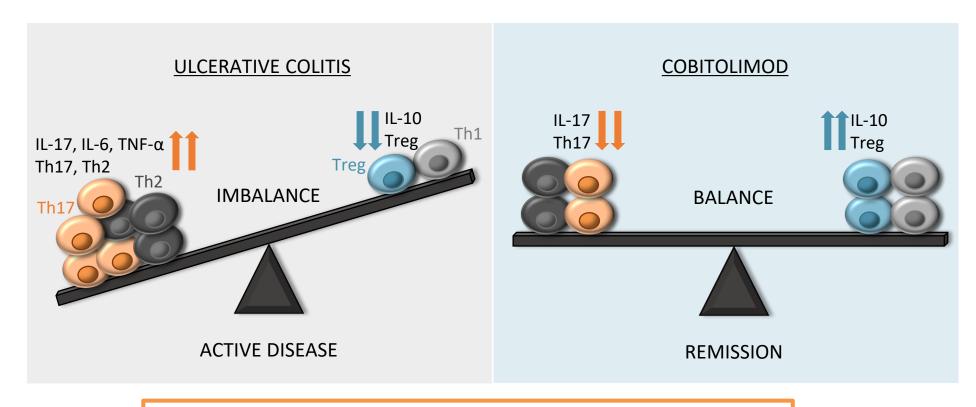


Modulation of the immune system

Local anti-inflammatory effect Healing of the colonic mucosa



Cobitolimod Induces Anti-Inflammatory Effects that Balances the Immune System in UC



Schmitt H. et al. J Crohns Colitis, 2020 May 21;14(4):508-524



Conclusions from Phase IIb Study

- Clinically relevant efficacy, comparable to other advanced therapies
 - Met the primary endpoint for the highest dose, 250 mg x 2
 - Supportive findings in secondary endpoints
- Excellent safety profile



Phase IIb Published in the Lancet Gastroenterology & Hepatology





Strong Support for Phase III Development



Successful FDA & EMA Interactions

• Both FDA and EMA endorse the advancement of cobitolimod into phase III studies in patients with moderate to severe left-sided ulcerative colitis



Strong Support from Key Opinion Leaders

Active North American and European advisory boards

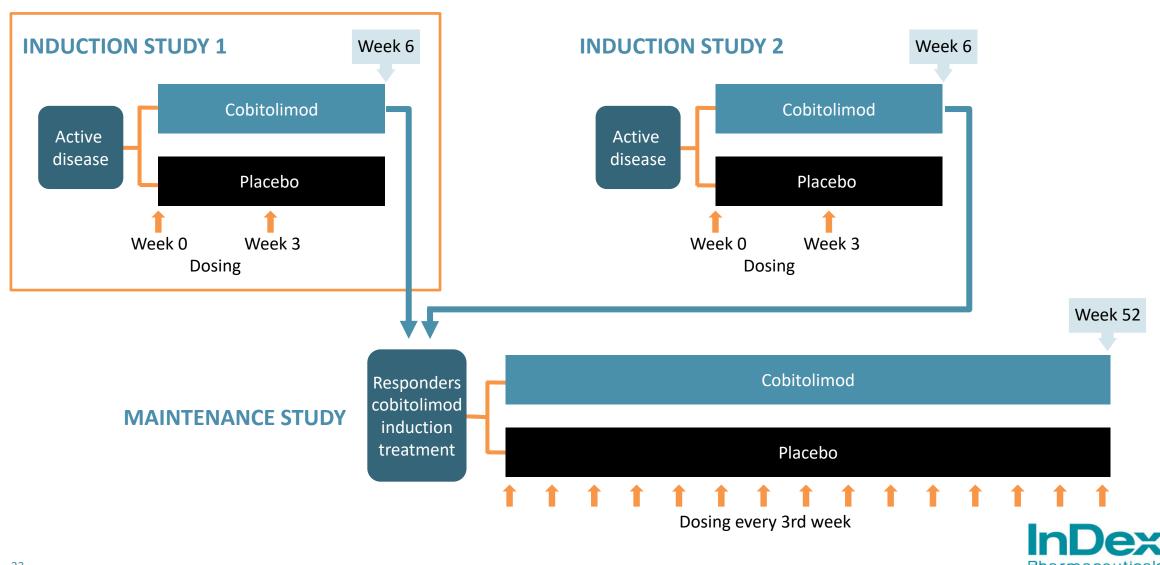


Primary Market Research Support Blockbuster Potential

- Cobitolimod's efficacy/safety ratio considered unsurpassable by gastroenterologists
- Likely to prescribe cobitolimod to a significant proportion of their patients
- Payers confirm pricing in line with recently launched advanced ulcerative colitis therapies



Cobitolimod Phase III Program for Left-Sided Ulcerative Colitis Sequential Execution Provides Key Advantages



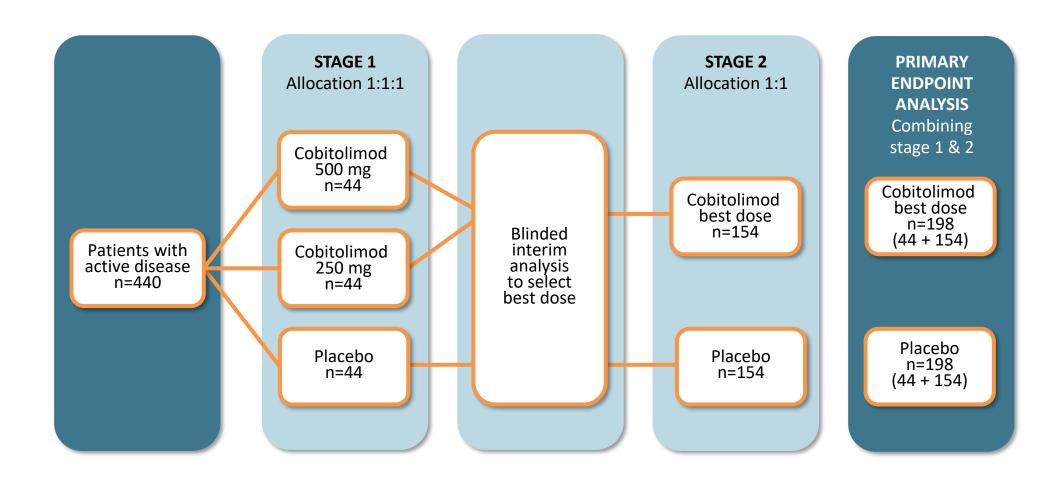
Induction Study 1 Design Building on Successful Phase IIb Study

- Moderate to severe active left-sided UC
- Have failed conventional and/or advanced treatment, e.g. biologics/JAK inhibitor
- Dosing at week 0 and 3
 - Evaluating both 250 mg and 500 mg dose in an adaptive design
 - Higher dose can increase efficacy further
- Primary endpoint clinical remission at week 6
 - Defined by the 3-component Mayo score, i) rectal bleeding of 0, ii) stool frequency of 0 or 1 (with at least one point decrease from Baseline, Week 0), and iii) endoscopy score of 0 or 1
- Safety endpoints
 - Incidence of AEs and SAEs, Vital signs, Physical examination, Laboratory findings



Induction Study 1 – Adaptive Design







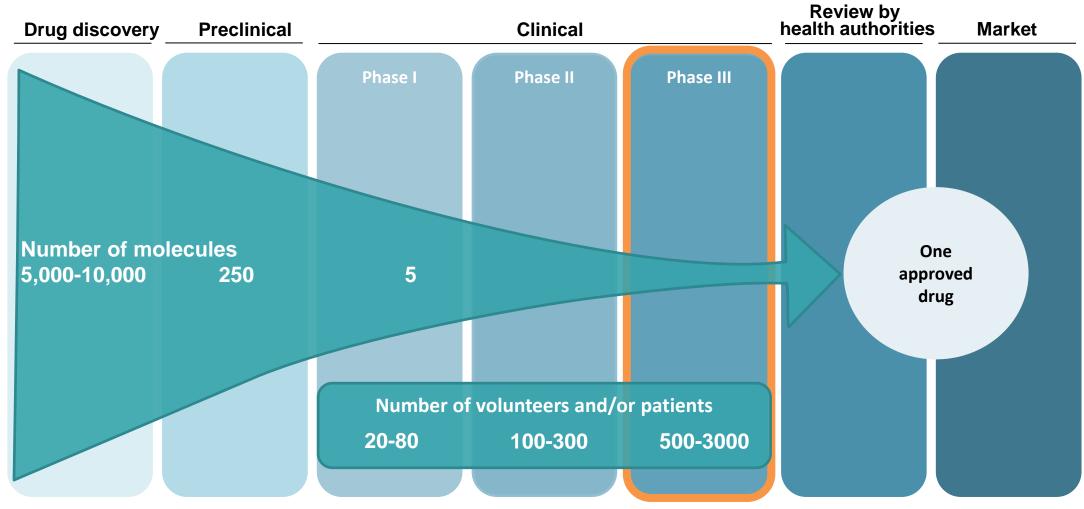




CONCLUDE Execution

Pernilla Sandwall, COO Anders Bröijersen, Senior Medical Director

Phase III - Last Phase of Development Before Marketing Application



Source: Hay M, et al. vol 32,Nr 1, 2014, Nature biotechnology. Clinical development success rates for investigational drugs and David Taylor, The Pharmaceutical Industry and the Future of Drug Development, in Pharmaceuticals in the Environment, 2015, pp. 1-33.

Successful Execution in Previous Phase IIb Study

- 213 patients at 91 clinics in 12 European countries
- Competitive recruitment rate in line with concurrent phase III studies in UC
- Professor Raja Atreya, University of Erlangen-Nürnberg as Principal Investigator
- Parexel as CRO





The InDex Way – a Very Proactive Model

- Experienced InDex core Clinical Operations Team
- Close collaboration with Parexel's project team as well as Clinical Research Associates (CRAs)
- Direct engagement with nurses and physicians at the clinics to build team spirit
- Site focus streamline processes to simplify study execution for the clinics and patients
- Maintains high study quality and efficiency





Senior Medical Director

Anders Bröijersén, MD, PhD



- Board Certificate in Internal Medicine, trained at the Karolinska University Hospital
- PhD in Clinical Pharmacology, Karolinska Institute 1996
- +30 years in Academic and Pharma Life Science
- +15 years in pharmaceutical industry on National, Regional and Global levels
- Experience from Medical Affairs, Clinical Development & Pharmacovigilance



CONCLUDE Study Plan



- First phase III study including 440 patients at a few hundred sites in over 30 countries
- Parexel as global CRO ensures continuity
- Results expected H2 2023
 - First patient enrolled at the end of 2021
 - Interim analysis to select best dose after 30% of the patients
- Maintenance study running in parallel



Current Priorities

conclude

- Gain approval in each country and activate clinics
- Establish close relationship with clinics
- Pandemic easing up and clinics eager to get started
- Ukraine and Russia on hold
 - Working actively with Parexel on contingency plan
 - Planned to contribute 10-15% of patients



Selected countries in blue and orange, where orange means approvals in place



Factors Underpinning Successful Execution

conclude

- Experienced team with a proven model
- Close collaboration and strong support from top Key Opinion Leaders
- Uniqueness of cobitolimod
 - Novel Mechanism of Action
 - Focus on left-sided disease, majority of UC patients
 - Competitive efficacy with excellent safety profile



Professor William SandbornMedical Advisor CONCLUDE



Professor Walter Reinisch Medical Advisor CONCLUDE



Professor Raja Atreya
Principal Investigator CONCLUDE



Q&A

Questions

Write your question in the chat for the event



Investment Opportunity



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COBITOLIMOD IN PHASE III

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