



# InDex Pharmaceuticals

## *Pareto Securities Health Care Conference*

*September 2, 2021*

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**Should not Felicia and  
other patients with  
ulcerative colitis  
get the chance to  
live a normal life?**

# InDex Pharmaceuticals in Brief

- Cobitolimod for ulcerative colitis advancing into phase III
- Broad portfolio of pre-clinical stage assets from DIMS platform
  - DNA based ImmunoModulatory Sequences
- Listed on the Nasdaq First North Growth Market Stockholm (ticker INDEX)
- Oversubscribed rights issue in Q1 2021 of 63 MUSD to finance phase III development
- Market cap ~95 MUSD
- Main shareholders: Linc, HBM, 4th AP Fund, Handelsbanken

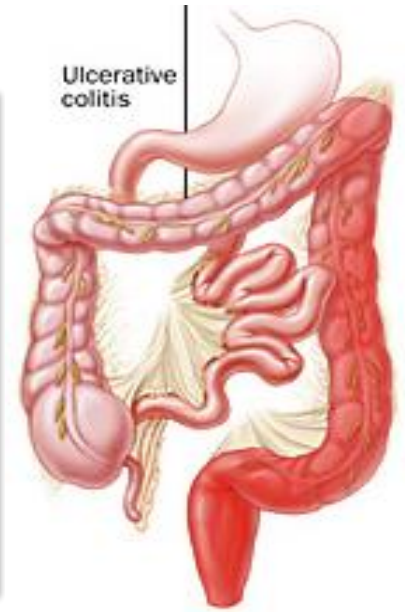


Cobitolimod



# Ulcerative Colitis – a Debilitating Disease with High Unmet Medical Need

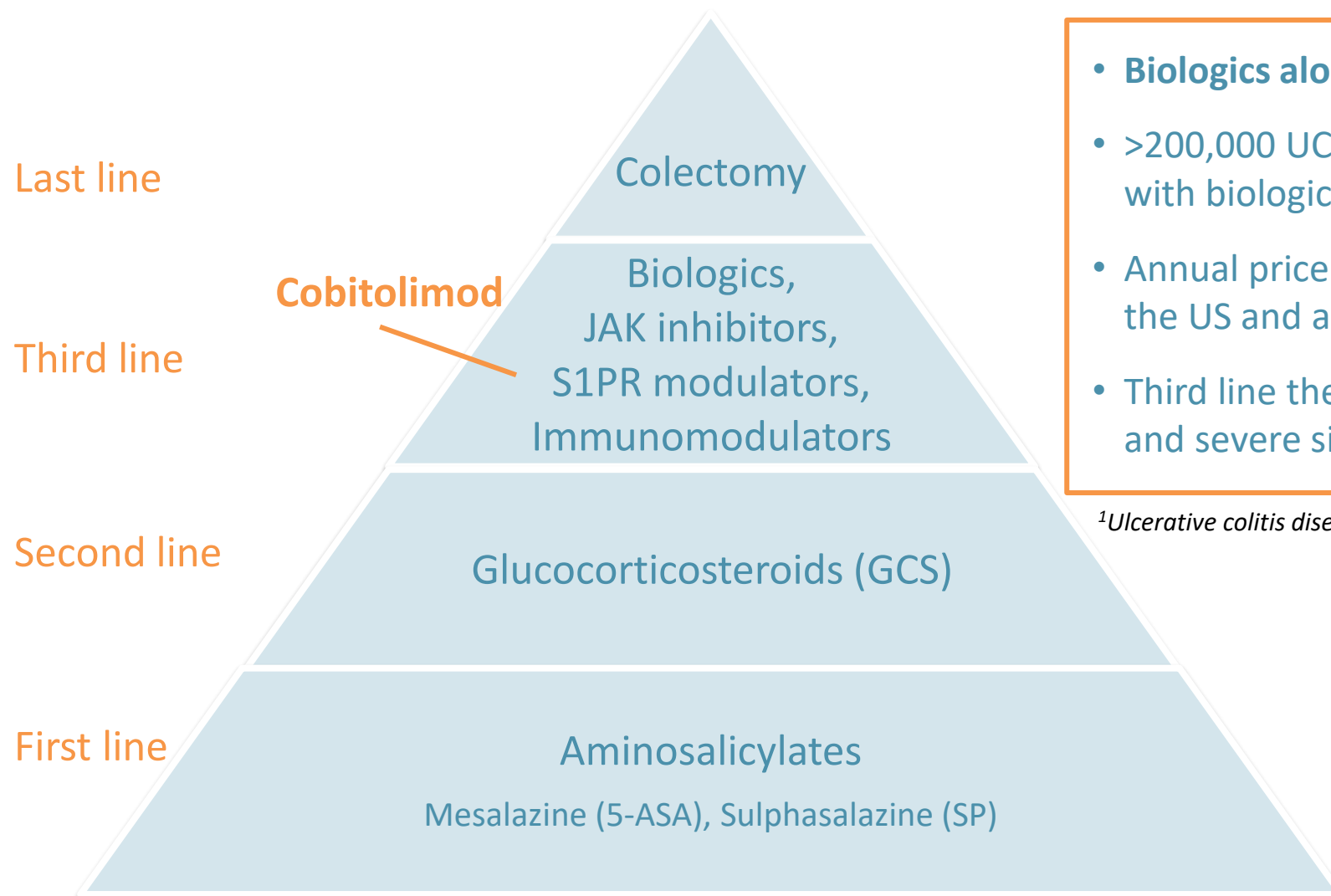
- Chronic inflammation of the colonic mucosa leading to ulcers
- Recurrent with active and inactive periods
- Very frequent blood- and mucus-mixed loose stools
- Current therapies for moderate to severe ulcerative colitis have limited efficacy and can cause severe side effects



*“The worst thing about having ulcerative colitis is probably not knowing. The flares, i.e. the periods 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*

# Moderate to Severe UC Is a High Value Market



- **Biologics alone sell for USD >5 Bn per year in UC<sup>1</sup>**
- >200,000 UC patients globally receive treatment with biologics<sup>1</sup>
- Annual price for biologics is USD 30,000-80,000 in the US and around EUR 10,000 in EU
- Third line therapies have problems with tolerance and severe side effects

<sup>1</sup>Ulcerative colitis disease coverage. Datamonitor Healthcare 2016

# Cobitolimod – First-in-Class Treatment with High Market Potential

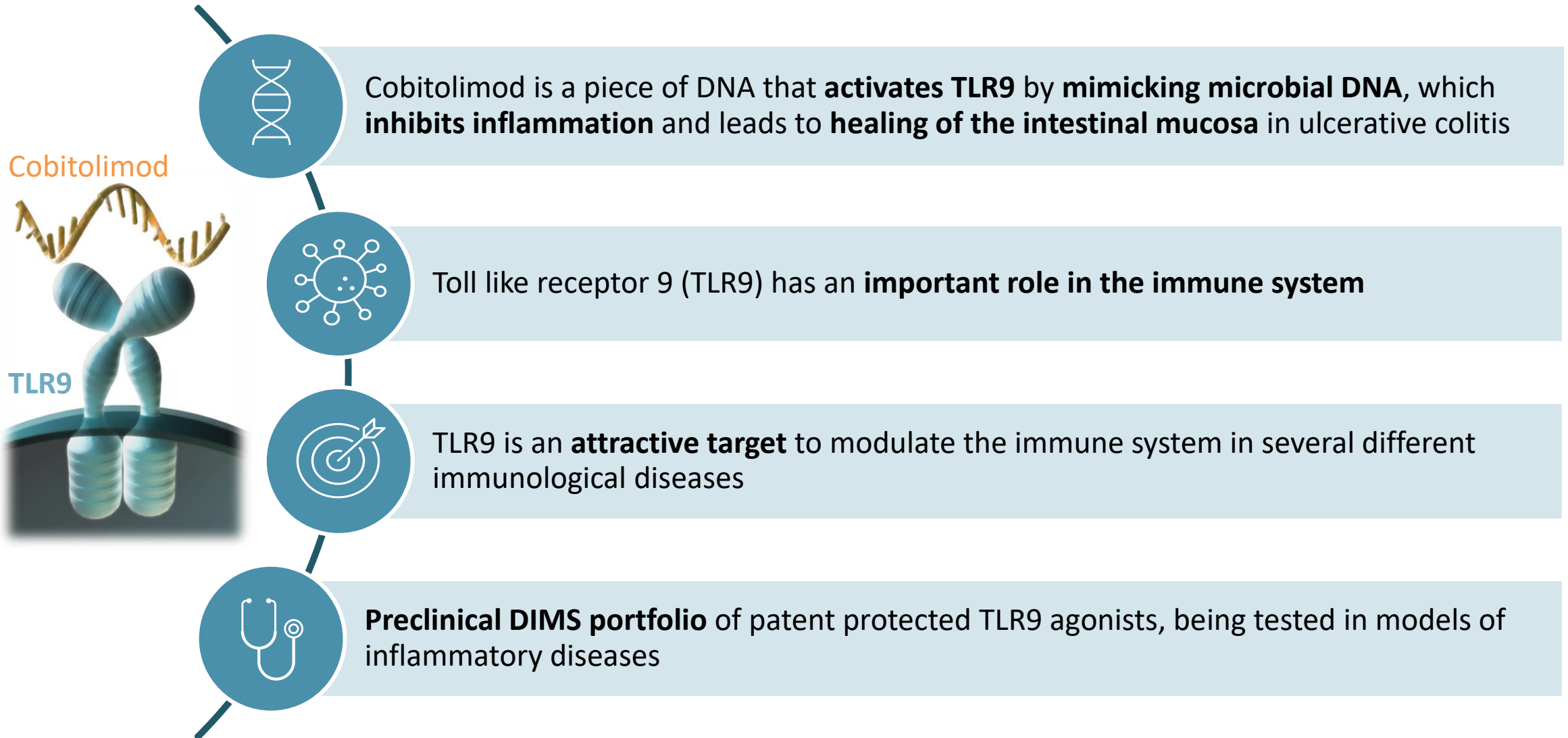
- Cobitolimod is a potential new medication for moderate to severe ulcerative colitis
- Primary endpoint met in phase IIb study with an excellent safety profile
- 4 previous completed clinical studies support efficacy and safety demonstrated in phase IIb
- Advancing into phase III

- Competitive efficacy
- Superior safety profile
- Local treatment, infrequent dosing
- Novel mechanism of action
- Potential for combination therapy



Cobitolimod has blockbuster potential with an outstanding combination of efficacy and safety

# Novel Mechanism of Action that Activates TLR9

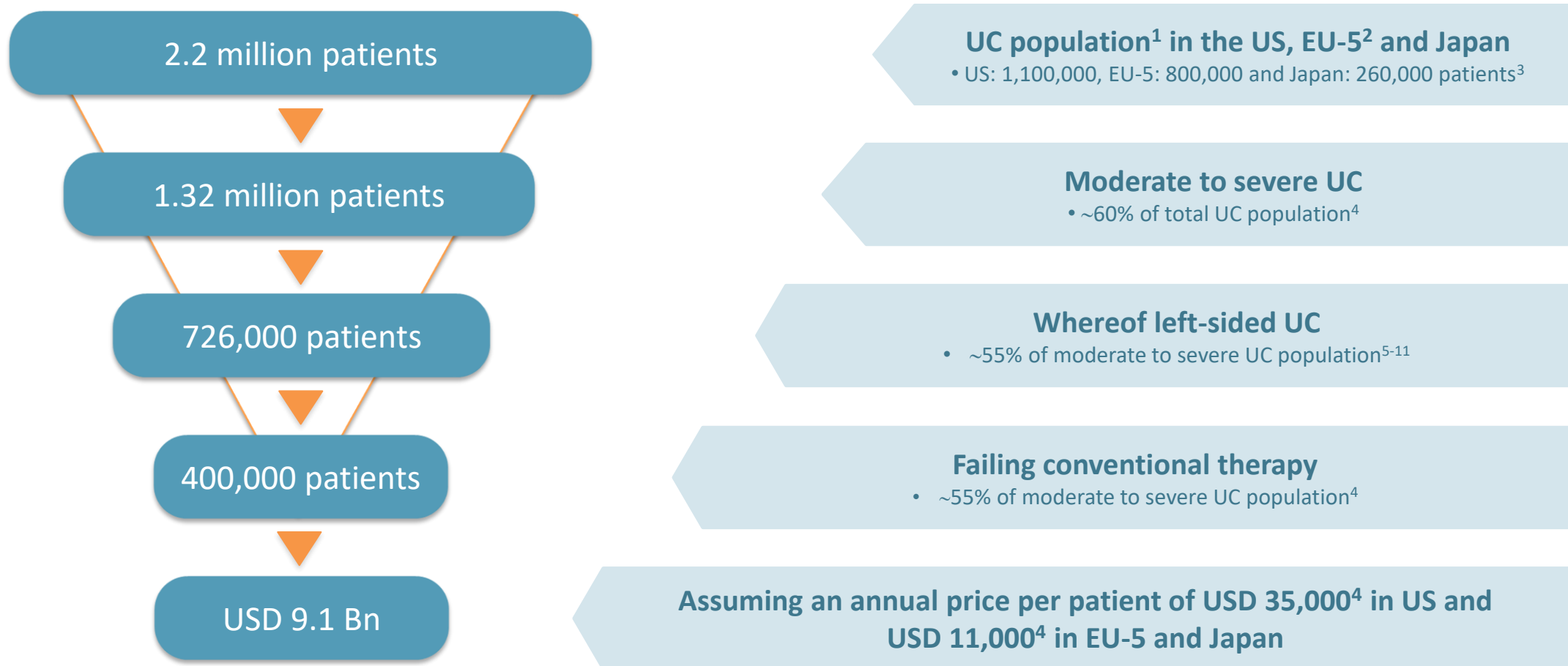




## Phase IIb Results Published in the Lancet Gastroenterology and Hepatology

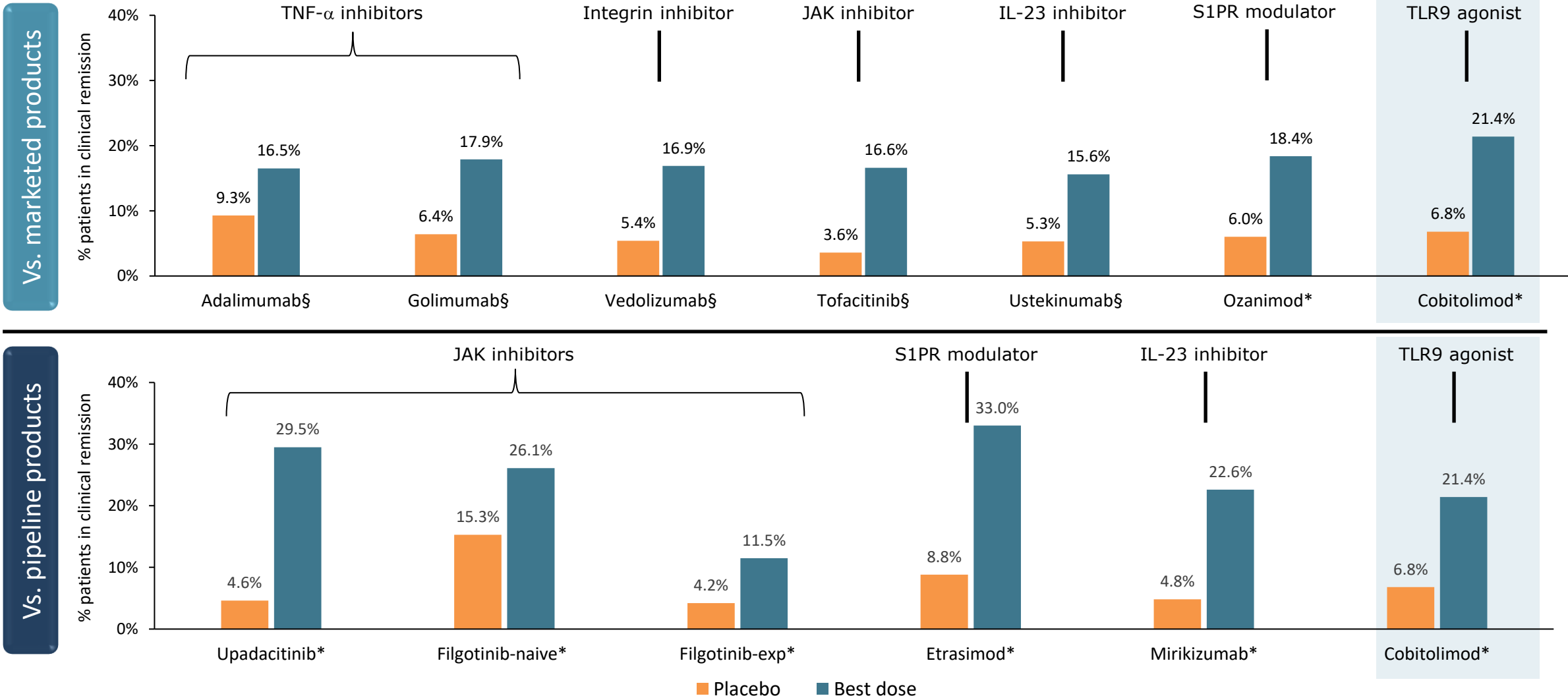


# Cobitolimod Addresses a USD >9 Bn Market



Notes: 1) Above 18 years of age. 2) EU-5 countries (France, Germany, Italy, Spain and the UK). 3) Global Data Ulcerative Colitis prevalence. 4) Apex Market Research 2020 5) Rutgeerts et al. N Engl J Med 2005;353:2462-76, 6) Sandborn et al. Gastroenterology 2012;142:257-265, 7) Sandborn et al. Gastroenterology 2014;146:85-95, 8) Feagan et al. N Engl J Med 2013;369:699-710, 9) Sandborn et al. N Engl J Med 2017;376:1723-36, 10) Sandborn et al. N Engl J Med 2019;381:1201-14, 11) Atreya et al. JCC 2016 Nov;10(11):1294-1302.

# Cobitolimod has Competitive Efficacy vs. Marketed Products and Late Stage Pipeline



§ Full Mayo Score  $\leq 2$ , \*3-component Mayo Score  $\leq 2$ . Caution advised when comparing data across clinical studies. The patient population in the studies included a mix of both biological naïve and biological experienced patients, except for filgotinib where separate studies were performed. Infliximab excluded from comparison as not comparable phase III patient population.

# Safety Concerns with Other Drug Classes

DRUG CLASS	SAFETY PROFILE
TNF- $\alpha$ inhibitors	Infections, malignancies, skin disorders
Integrin inhibitors	Infections, hypersensitivity reactions
JAK inhibitors	Infections, cancer, tears (perforation) in the stomach or intestines, pulmonary embolism
IL-23 inhibitors	Infections, malignancies
S1PR modulators	Infections, cardiac effect, elevated liver transaminase

# Cobitolimod is Now Advancing into Phase III



## **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**

- North American and European advisory boards established



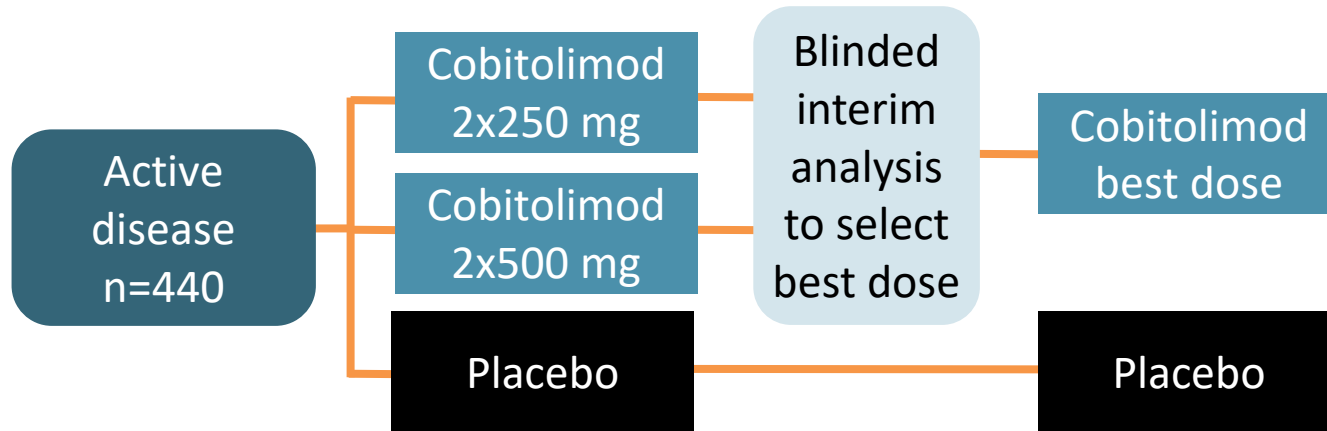
## **Primary Market Research Support Blockbuster Potential**

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



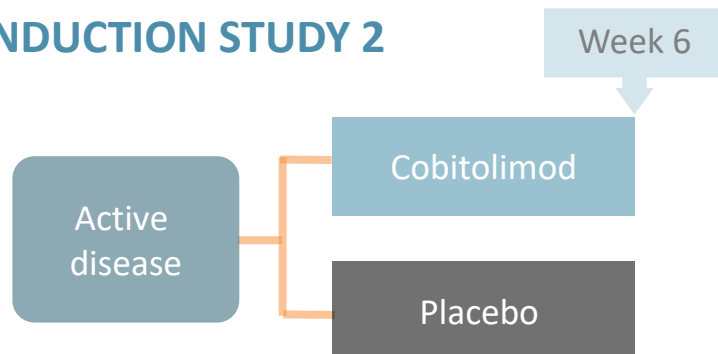
# Phase III Design

## INDUCTION STUDY 1 – ADAPTIVE DESIGN

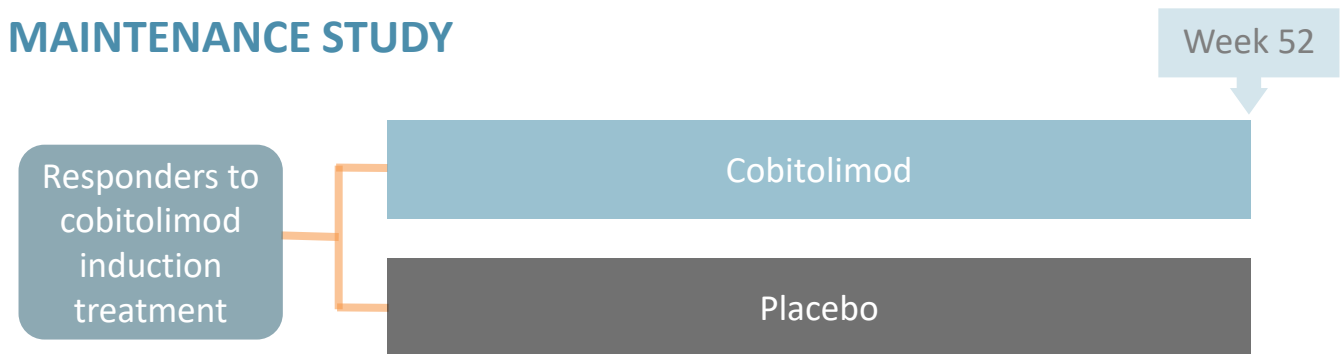


- Moderate to severe, left-sided ulcerative colitis
- Have failed conventional treatment and/or biologics/JAK inhibitor
- Dosing at week 0 and 3
- Primary endpoint clinical remission at week 6

## INDUCTION STUDY 2



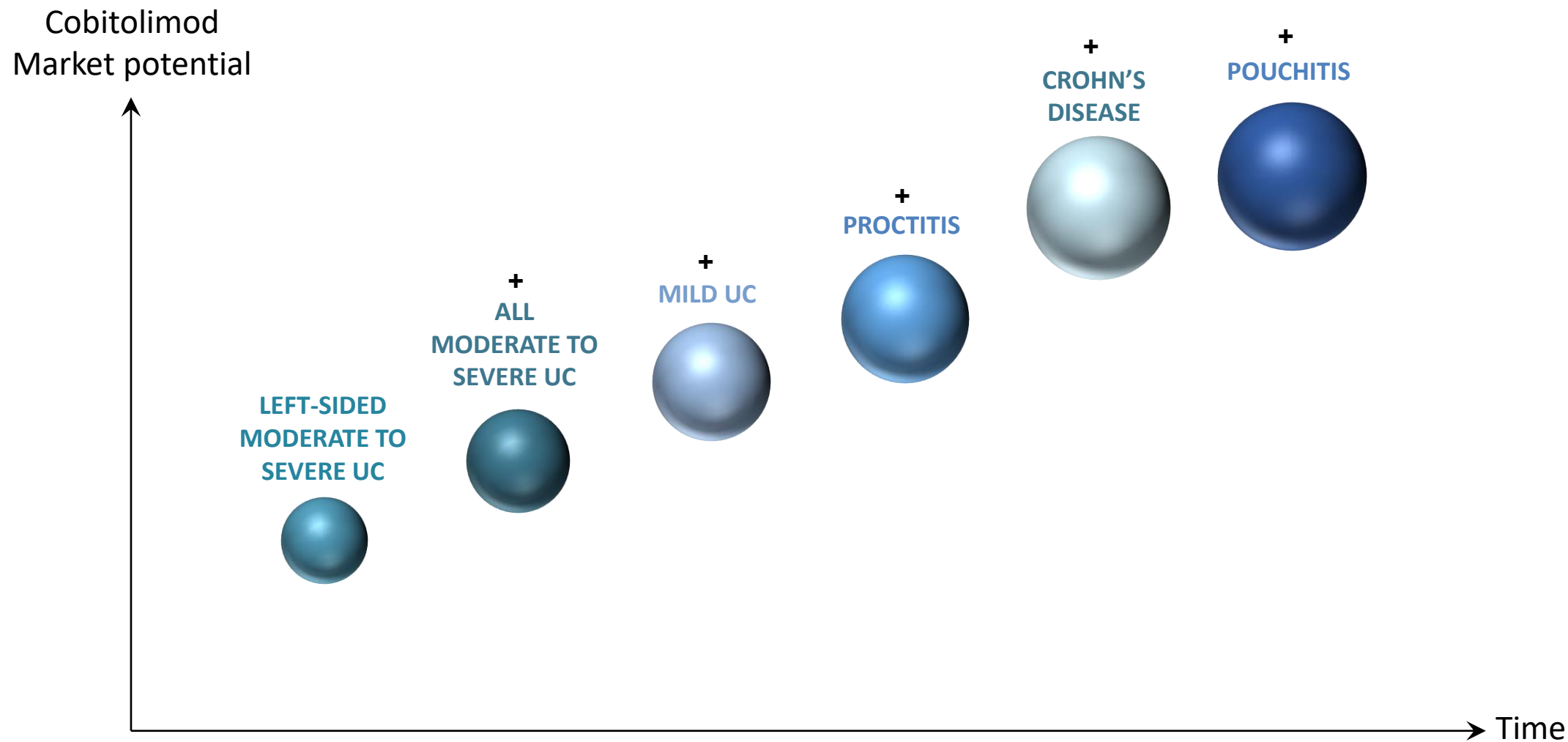
## MAINTENANCE STUDY



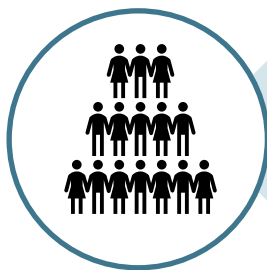
# The Phase III Study CONCLUDE

- Study design based on the successful phase IIb study
- Higher dose can increase efficacy further
- Global study including a few hundred sites in over 30 countries
- Agreement for services with leading global CRO
- Regulatory approval to start received in the US and Sweden, other countries ongoing
- Patient recruitment will be initiated after the summer
- 18-24 months to complete first induction study from initiation
- Financing secured by oversubscribed rights issue in Q1 2021

# High Market Potential with Market Expansion Possibilities



# Investment Opportunity



## MAJOR SUFFERING AND SOCIAL ECONOMIC COSTS

- 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 addresses a USD >9 Bn Market
- Cobitolimod has blockbuster potential with an outstanding combination of efficacy and safety and a novel mechanism of action



## COBITOLIMOD ADVANCING INTO PHASE III

- Patient recruitment will be initiated after the summer
- Financing secured until next pivotal read-out of clinical data

# Q&A





# CONTACT INFORMATION

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