



## **InDex Pharmaceuticals**

Pareto Securities' 10th annual Health Care Conference

September 5, 2019

### 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.



### InDex Pharmaceuticals in Brief

- Cobitolimod for ulcerative colitis in late stage clinical development
  - Primary endpoint met in the Phase IIb study CONDUCT (announced Aug 27)
  - Outstanding combination of efficacy and safety
  - First-in-class TLR9 agonist
  - Advancing cobitolimod towards phase III
- Based in Stockholm, Sweden with origins from Karolinska Institutet
  - Focus on immunological diseases with high unmet medical need
  - Broad portfolio of pre-clinical stage assets from DIMS platform
  - Very experienced Board and Management

• Listed on the Nasdaq First North Growth Market (ticker INDEX)



Cobitolimod

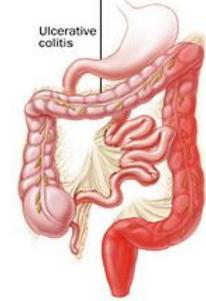


## Ulcerative Colitis – a Debilitating Disease with High Unmet Medical Need

- Ulcerative colitis is an inflammatory bowel disease (IBD) with 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

"I always need to be close to a toilet, which restricts my life significantly. The worst is to be so socially disabled. I would like to be spontaneous and just live my life without worrying about my stomach and toilet visits",

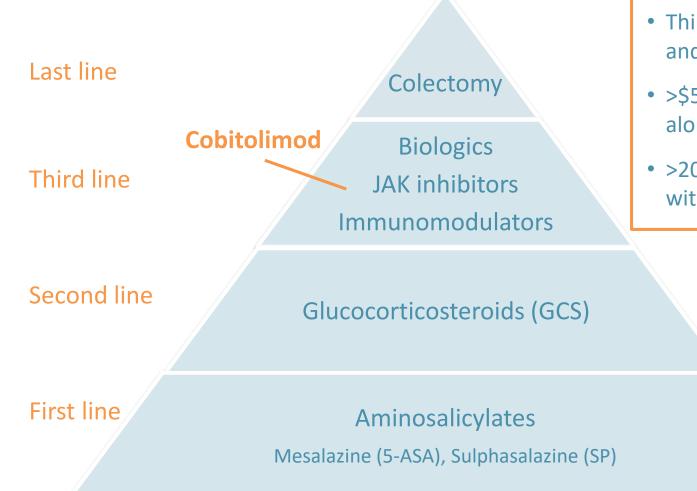
*Emma, 24 years old suffering from ulcerative colitis* 







## Clear Need for Safer and More Efficacious Drugs in Moderate to Severe UC



- Third line therapies have problems with tolerance and severe side effects
- >\$5 Bn per year of biologics sales globally in UC alone<sup>1</sup>
- >200,000 UC patients globally receive treatment with biologics<sup>1</sup>

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



### Cobitolimod – InDex's Lead Drug Candidate

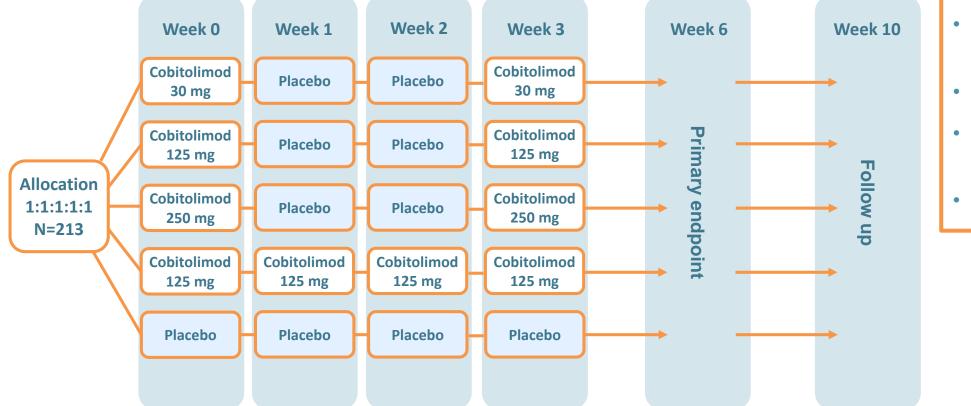
- Cobitolimod is a potential new medication for moderate to severe ulcerative colitis
- Primary endpoint met in Phase IIb study CONDUCT with an excellent safety profile
- 4 previous completed clinical studies support efficacy and safety demonstrated in CONDUCT

- Competitive efficacy
- Excellent safety, very low systemic uptake
- Local treatment, provides rapid onset of action
- Novel mechanism of action (MoA)
- Potential for combination therapy

Cobitolimod has high market potential with an outstanding combination of efficacy and safety



#### Phase IIb Study Design



- Moderate to severe active left sided UC
- Failed 5-ASA/SP and GCS
- Failed immunomodulators and/or biologics
- No concomitant biologics

Exploratory study to identify best dosing regimen for phase III

CObitolimod as Novel DNA-based Ulcerative Colitis Treatment

conduct

## Met Primary Endpoint with Competitive Efficacy

|                               | COBITOLIMOD         |                      |                      |                      |                   |
|-------------------------------|---------------------|----------------------|----------------------|----------------------|-------------------|
| Clinical Remission at Week 6* | 30 mg x 2<br>(n=40) | 125 mg x 2<br>(n=43) | 125 mg x 4<br>(n=42) | 250 mg x 2<br>(n=42) | PLACEBO<br>(n=44) |
| % of patients                 | 12.5 %              | 4.7 %                | 9.5 %                | 21.4 %               | 6.8 %             |
| Δ to placebo                  | 5.7 %               | -2.1 %               | 2.7 %                | 14.6 %               |                   |
| Odds Ratio                    | 2.0                 | 0.7                  | 1.4                  | 3.8                  |                   |
| P-value two-sided test        | n.s.                | n.s.                 | n.s.                 | 0.0495               |                   |
| P-value one-sided test        | n.s.                | n.s.                 | n.s.                 | 0.0247               |                   |

Full analysis set, \*Clinical Remission at Week 6 defined as Modified Mayo sub scores: i) rectal bleeding of 0, ii) stool frequency of 0 or 1 and iii) endoscopy score of 0 or 1 (excluding friability)

Sensitivity analyses confirm the robustness of the primary endpoint findings



## **Excellent Safety Profile**

| Treatment Emergent                   | COBITOLIMOD         |                      |                      |                      |                   |
|--------------------------------------|---------------------|----------------------|----------------------|----------------------|-------------------|
| Adverse Events<br>No of patients (%) | 30 mg x 2<br>(n=40) | 125 mg x 2<br>(n=43) | 125 mg x 4<br>(n=42) | 250 mg x 2<br>(n=42) | PLACEBO<br>(n=44) |
| Patients with AEs                    | 10 (25.0%)          | 17 (39.5%)           | 15 (35.7%)           | 18 (42.9%)           | 21 (47.7%)        |
| Patients with Serious AEs            | 2 (5.0%)            | 0                    | 2 (4.8%)             | 4 (9.5%)             | 2 (4.5%)          |
| Deaths                               | 0                   | 0                    | 0                    | 0                    | 1 (2.3%)          |

Safety analysis set, some patients have reported several adverse events



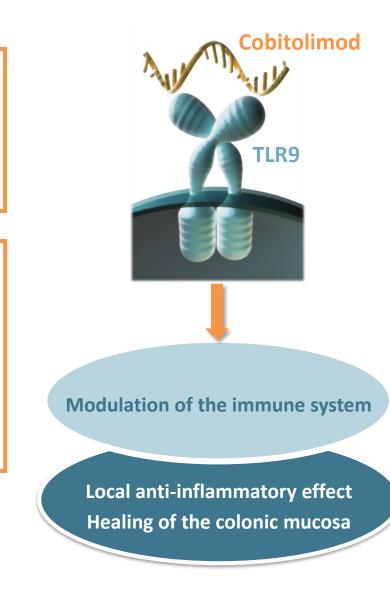


## Cobitolimod is a First-in-Class TLR9 Agonist

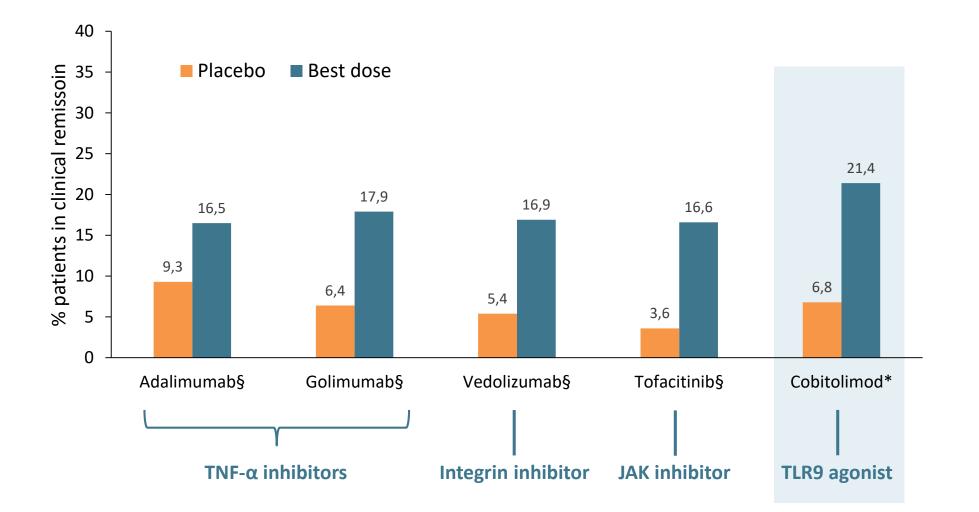
Cobitolimod is an oligonucleotide which activates Toll Like Receptor 9 (TLR9) by mimicking microbial DNA

#### 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



## Cobitolimod has Competitive Efficacy vs. Marketed Products

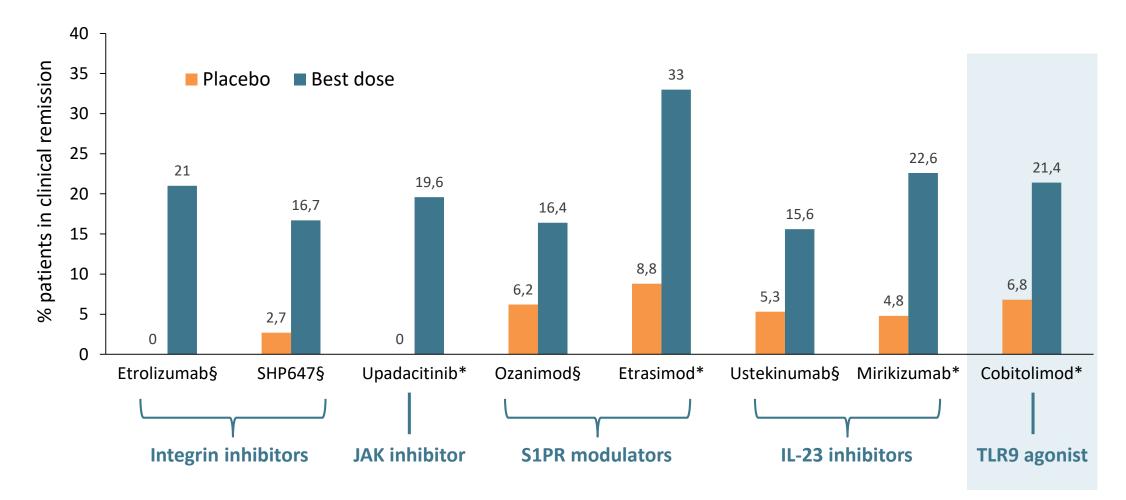


§ Full Mayo Score ≤2, \*3-component Mayo Score ≤2

NOTE: Infliximab excluded from comparison as not comparable phase III patient population



## Cobitolimod has Competitive Efficacy vs. Late Stage Pipeline



§ Full Mayo Score ≤2, \*3-component Mayo Score ≤2



## Safety Concerns with Other Drug Classes

#### DRUG CLASS SAFETY PROFILE

| TNF-α inhibitors | Infections, | malignancies, | skin | disorders |
|------------------|-------------|---------------|------|-----------|
|------------------|-------------|---------------|------|-----------|

| JAK inhibitors | Infections, cancer, tears (perforation) in the stomach or intestines, pulmonary |
|----------------|---|
|                | embolism  |

S1PR modulators Heart rate effect, elevated liver transaminase

IL-23 inhibitors Infections, malignancies



## Next Steps in Cobitolimod Development

#### Prepare for phase III

- Analyze full CONDUCT data set Q4 2019
- Regulatory interactions Q1 2020
- Protocol development Q1 2020
- CRO selection Q1 2020
- Study drug manufacturing H1 2020
- Additional tox studies H1 2020
- Planned First-Patient-In H2 2020

#### Evaluate best route to commercialization

- Set up InDex sponsored phase III program based on sequential design
  - Stepwise financing, additional de-risked inflection points
- Business development to continue in parallel



### IBD is a High Value Therapeutic Area

|      | RECENT DEALS IN IBD/INFLAMMATION |          |            |                    |                   |  |
|------|----------------------------------|----------|------------|--------------------|-------------------|--|
| YEAR | COMPANY                          | PARTNER  | COMPOUND   | MOA                | CLINICAL<br>PHASE | TERMS  |
| 2015 | Receptos                         | Celgene  | Ozanimod   | S1PR modulator     | Phase II          | \$7.2 billion (acquisition)  |
| 2015 | Galapagos                        | Gilead   | Filgotinib | JAK inhibitor      | Phase II          | \$300 million upfront + \$425 million equity<br>investment + \$1.35 billion milestones + tiered<br>royalty starting at 20% |
| 2016 | Pfizer                           | Shire    | SHP647     | Integrin inhibitor | Phase II          | \$90 million upfront + \$460 million milestones<br>+ royalty   |
| 2016 | MedImmune/<br>Astra Zeneca       | Allergan | Brazikumab | IL-23 inhibitor    | Phase Ila         | \$250 million upfront + \$1.27 billion<br>milestones + royalty   |
| 2018 | Theravance                       | 181      | TD-1473    | JAK inhibitor      | Phase I           | \$100 million upfront + \$900 million<br>milestones + royalty  |



## **Oral Formulation Development**

#### • New GMP ready capsule for oral administration of cobitolimod

- Targeted delivery to the colon
- Core matrix in a capsule with a pH sensitive coating
- Dissolution profile similar to leading 5-ASA products
- Ability to modify and adapt the release profile
- Additional IP

#### • Potential follow-on product to the topical formulation in CONDUCT

- Patient convenience
- Broadened potential therapeutic use in new indications



#### **Board of Directors with Proven Track Records**

#### **Dr. Wenche Rolfsen**

Chairman of the Board since 2011 Chairman of BioArctic and Board member of Swedish Match Previously leading positions at Pharmacia and Quintiles

#### Dr. Uli Hacksell

Director since 2015 CEO of Medivir. Board member of Medivir, Active Biotech, Cerecor, Adhera Therapeutics and Uppsala University Previously CEO of Cerecor, ACADIA and executive positions at Astra

#### **Dr. Lennart Hansson**

Director since 2011 Chairman of Ignitus and Sixera Pharma. Board member of Medivir, Calliditas Therapeutics, Athera Biotechnologies and Cinclus Pharma Previously Head of Life Science Investments at Industrifonden, CEO of Arexis, senior positions at Astra

#### Stig Løkke Pedersen

#### Director since 2012

Chairman of Transmedia, Modus Therapeutics, moksha8 Ltd, and SSI-Diagnostics. Board member of Union Therapeutics, MSI Ltd, SkyBrands and BroenLab Previously Chief Commercial Officer at Lundbeck, chairman of Nuevolution





#### Management Team with Broad Experience



Johan Giléus, CFO Previously partner at Deloitte **Pernilla Sandwall, COO** Previously leading positions within Clinical Operations at Merck&Co/MSD **Peter Zerhouni, CEO** Previously CEO and Head of Business Development at Diamyd Medical **Dr. Thomas Knittel, CMO** Gastroenterologist, previously Director Medical Marketing at Novo Nordisk



#### Financials H1 2019

- Revenues amounted to SEK 0.0 (0.1) million
- Operating result amounted to SEK –34.9 (–44.7) million
- Cash flow from operating activities amounted to SEK –32.5 (–42.6) million
- Cash and cash equivalents at the end of the period amounted to SEK 50.5 (82.5) million

All comparative amounts in brackets refer to the outcome of InDex's overall activities during the corresponding period 2018.





#### **InDex Strengths**

#### **BLOCKBUSTER POTENTIAL**

- Ulcerative Colitis (UC) is a debilitating disease with high unmet medical need
- Annual sales of biologics in UC amounts to >\$5 billion
- Therapeutic field with pronounced big pharma interest
- Cobitolimod has high market potential with an outstanding combination of efficacy of safety and a new MoA

#### LATE STAGE CLINICAL DEVELOPMENT

- Primary endpoint met in the Phase IIb study CONDUCT with competitive efficacy and excellent safety
- 4 previous completed clinical studies support efficacy and safety demonstrated in CONDUCT
- Phase III preparations launched for FPI H2 2020
- Cobitolimod validates broad portfolio of other DIMS assets with potential in inflammation

#### **EXPERIENCED BOARD & MANAGEMENT**

• Board and management with extensive experience from the pharmaceutical industry and listed companies



# **CONTACT INFORMATION**

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