

# COLLECT, clinical phase III study in chronic active treatment refractory Ulcerative Colitis

Kappaproct®, a DNA-based Immunomodulatory TLR9 Agonist

- Targeting an area of high unmet medical need
- Excellent Safety Profile
- Orphan status EU
- Companion Diagnostics

## Kappaproct (DIMS0150)

Kappaproct, a DNA-based immunomodulatory sequence (DIMS), is InDex Pharmaceuticals' lead compound for treatment of steroid resistant Ulcerative Colitis (UC). It is entering a phase III clinical trial for chronic active treatment refractory UC patients.

## Unmet Medical Need

Kappaproct has shown to be efficacious in patients with chronic active UC, whose remaining option is colectomy.

## Personalized Medicine

InDex Pharmaceuticals is developing a companion diagnostic to allow selection of patients who are most likely to benefit from treatment with Kappaproct.

## Orphan Drug Status

Kappaproct has received Orphan Drug Designation from the EMA.

## Excellent safety

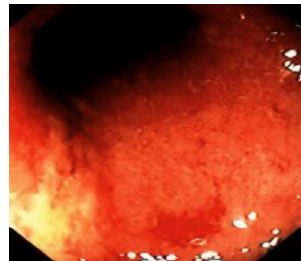
Through both animal toxicology and clinical studies, Kappaproct has demonstrated an excellent safety profile.

## Development history

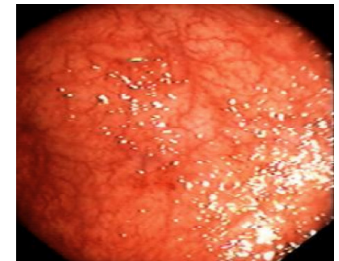
Efficacy data observed in the phase II clinical trial of Kappaproct for the treatment of steroid resistant UC:

- Single dose clinical remission after one week in 12% of patients. No clinical remission with placebo.
- Histological improvement in 35% of patients after four weeks. No improvement with placebo.
- Of all clinical responders in the treatment group 44% showed concomitant histological remission. No histological remission in placebo responders.

Under compassionate use 14 patients elected for radical surgery received Kappaproct in single or multiple dose. 71% (10/14) reached clinical remission at week 12.



Before treatment



One week post single rectal dose

## Phase III COLLECT study

A placebo-controlled, double-blind, randomized, study to assess the efficacy and safety of Kappaproct as an add-on to current practice in chronic active treatment refractory UC patients.

Study Size:	120 subjects randomized
Countries:	Czech Republic, Germany, Hungary, Italy, Poland, UK
Dosing regime:	Two doses of 30 mg 4 weeks apart
Primary Objective:	Clinical remission at week 12
Secondary Objectives:	Time to / rate of colectomy and safety / tolerability during 12 months

## Technology platform

InDex Pharmaceuticals develops DIMS sequences, synthetic oligonucleotides that induce immunomodulatory effects by binding to toll-like receptor (TLR) 9. The discovery of the TLR family was awarded with the Nobel Prize in Medicine in 2011.

InDex has a wide range of proprietary DIMS compounds with different immunomodulatory effects, unclosing many therapeutic possibilities.

DIMS are very easily drugable compounds, which in animal models have shown potent efficacy through several routes of administration.

