

# Unlocking disease modification in fibro-inflammation

*STENOVA Open-Label Extension (OLE) Study Results*  
*October 1, 2026*

**AGOMAB**

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This presentation includes forward looking statements, including without limitation, statements relating to the expected timing, design and readouts of our ongoing and planned preclinical studies and clinical trials, interim and topline data from our preclinical and clinical studies, the expected benefits of our product candidates, our ability to advance product candidates into, and successfully complete, clinical trials, potential future registrational endpoints, potential capital financing and our expected cash runway. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, strategy and plans, industry environment, potential growth opportunities, and our expectations for future operations, are forward looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," or the negative version of these words and similar expressions are intended to identify forward looking statements. We have based these forward looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short and long term business operations and objectives, and financial needs. These forward looking statements are subject to a number of risks, uncertainties and assumptions, including the results of our clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements for product candidates; the impact of governmental laws and regulations on our business; disruptions caused by our reliance on third party suppliers and service providers; the risk that our expectations and management's guidance regarding our cash position and runway and other financial estimates may be incorrect; and risks related to geopolitical conflicts and macro-economic events. These and other risks and uncertainties are described more fully in our filings and reports with the SEC, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward looking statements. We undertake no obligation to update publicly any forward looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations.

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*Funding:* NIH, Helmsley Charitable Trust, Crohn's and Colitis Foundation, UCB, Pliant, BMS, AbbVie, Pfizer, Boehringer Ingelheim, Morphic, Kenneth Rainin Foundation

# Today's speakers



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# Agenda



## 1. Introduction

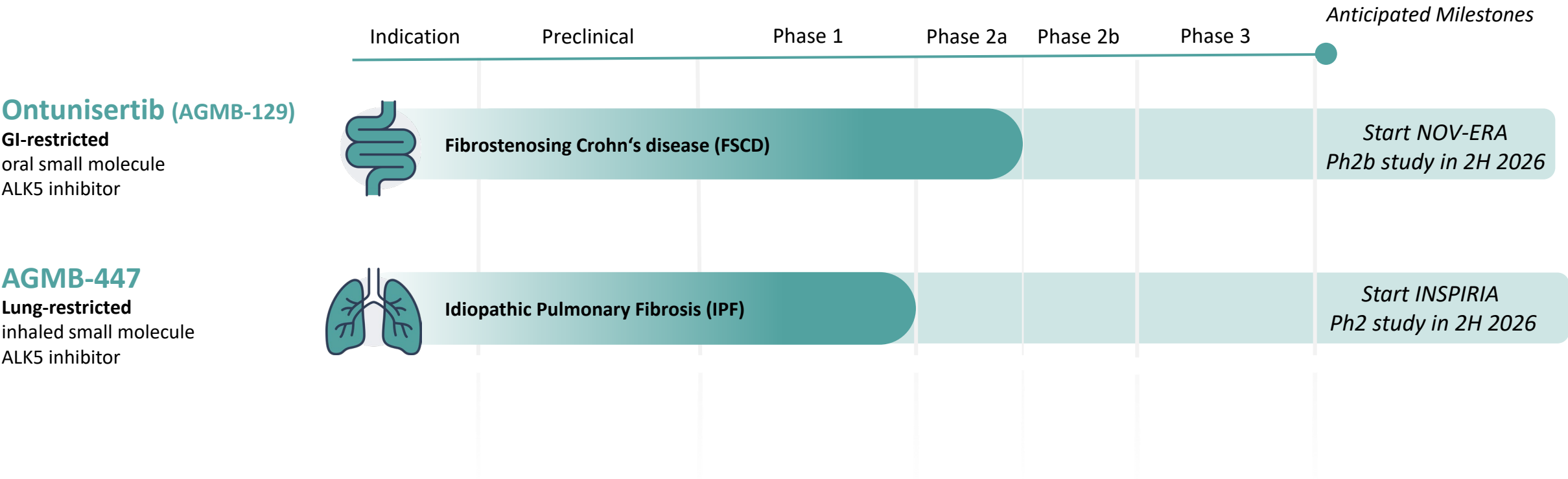
2. Fibrostenosing Crohn's disease & the unmet need in fibro-inflammation

3. STENOVA *Part B results*: Open-label extension (OLE) study with ontunisertib in FSCD

4. Next steps with ontunisertib

5. Q&A

# Focused pipeline of product candidates for fibro-inflammatory diseases



Note: ALK5, activin receptor-like kinase 5; GI, gastrointestinal; NOV-ERA, clinical trial name for Ph2b FSCD trial; INSPIRIA, clinical trial name for Ph2 IPF trial

# Agenda

1. Introduction

**2. Fibrostenosing Crohn's disease & the unmet need in fibro-inflammation**

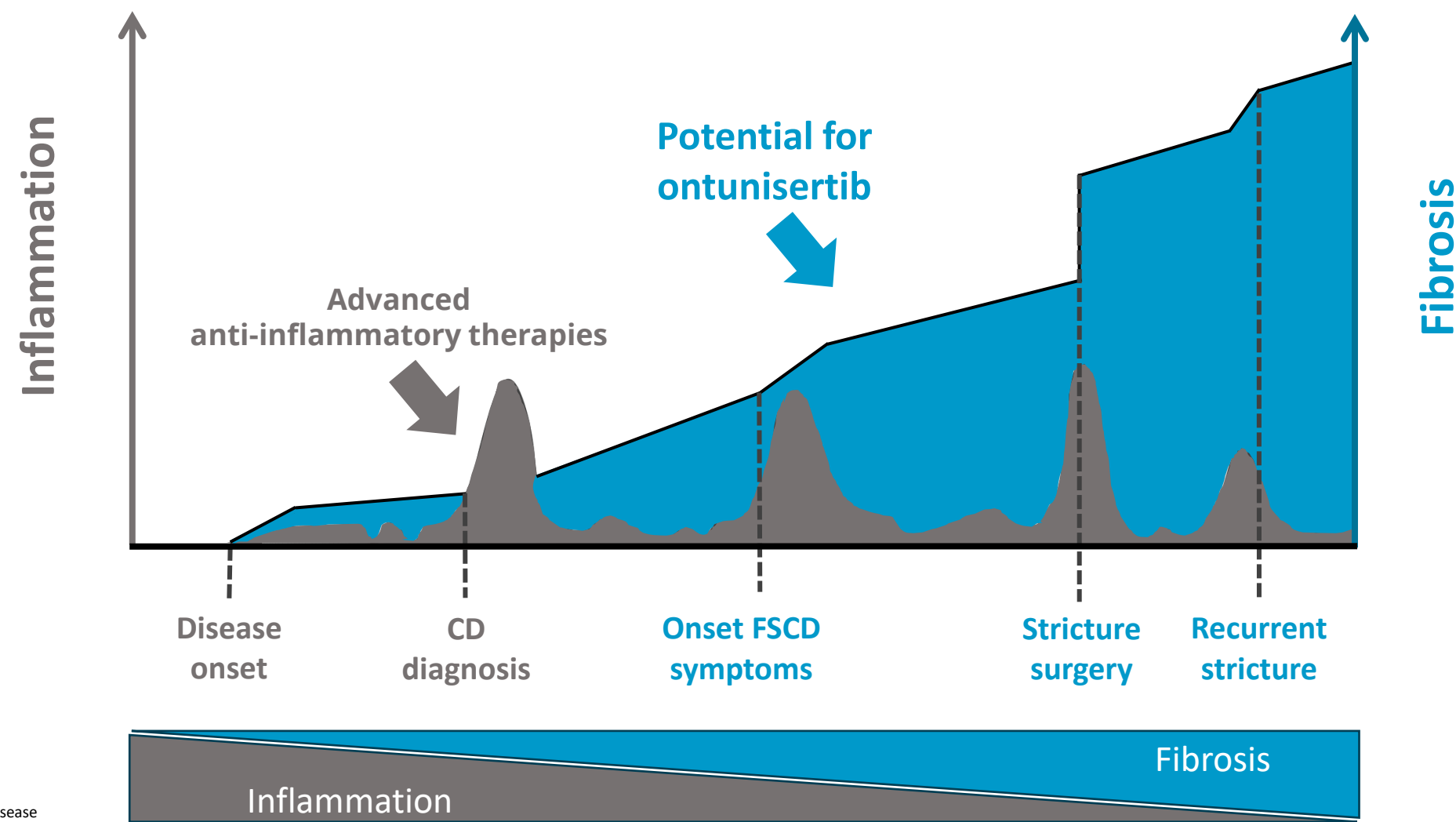
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# Fibro-inflammation drives disease progression in IBD

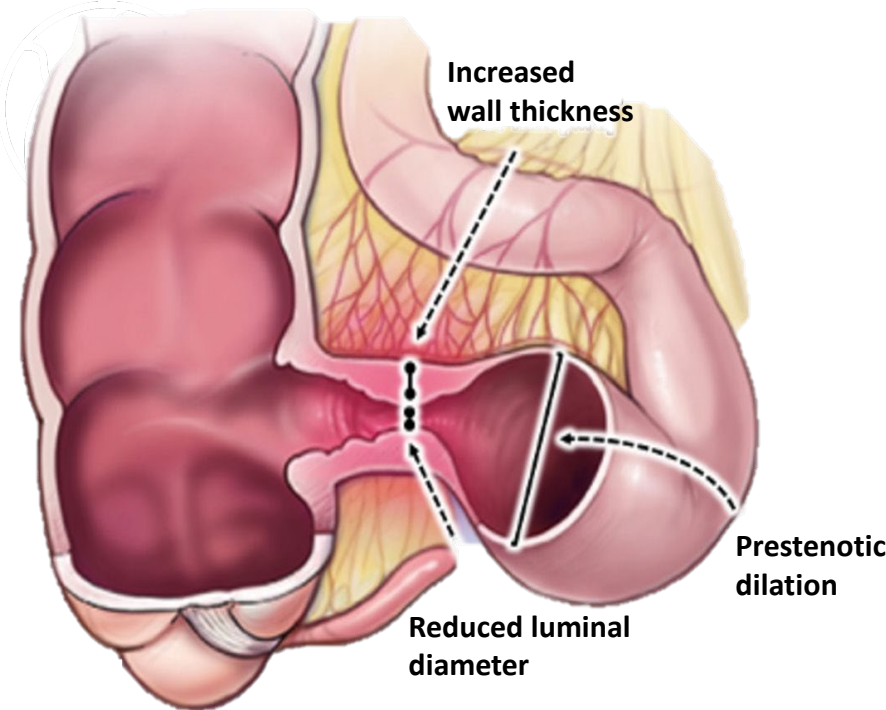
Current treatment paradigm focuses on treating inflammatory flares



IBD, Inflammatory Bowel Disease

# Fibrotic stricturing is the leading unresolved issue in Crohn's disease

## FIBROTIC STRICTURE IN CD PATIENT <sup>1</sup>



## PATIENT IMPACT



**Pain, cramps & vomiting after meals**



**Dietary changes**



**Surgery**

## PREVALENCE & COST BURDEN

**~46%**

Of all CD patients have Fibrostenosing Crohn's disease (FSCD) <sup>2</sup>

**~620,000**

patients with FSCD <sup>3</sup>

**>\$80K**

Higher healthcare costs per year vs 'inflammatory' CD <sup>4</sup>

**No pharmacological treatment approved for FSCD**

Sources: <sup>1</sup> [Bettenworth et al. 2019](#); <sup>2</sup> [Fan et al. IBD 2023](#); <sup>3</sup> Patients in the USA, EU4+UK and Japan, Census.gov (2032); Eurostat (2030), Japan census (2032), Ye 2020, Georgiadou 2019, GlobalData market report; <sup>4</sup> [Fan et al. JMCP 2023](#).

# FSCD's unmet need defines what a new therapy must deliver

## CURRENT STATUS

### Fibrosis remains untreated <sup>1,2</sup>

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- Inflammation control not enough  
Standard anti-inflammatory drugs have limited effect on fibrosis
- Main solutions: EBD and surgery  
Need for medicinal therapies

## UNMET MEDICAL NEED

### Restore normal everyday life <sup>3,4</sup>

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- Live free of symptoms — especially pain
- Restore normal diet and improve QoL
- Avoid surgery

## WHAT SHOULD A DRUG LOOK LIKE

### Designed for long-term use <sup>5,6</sup>

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- Safe
- Convenient oral dosing
- Compatible with standard of care

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## THE NEED A direct anti-fibrotic mechanism with a safe, oral, combinable profile

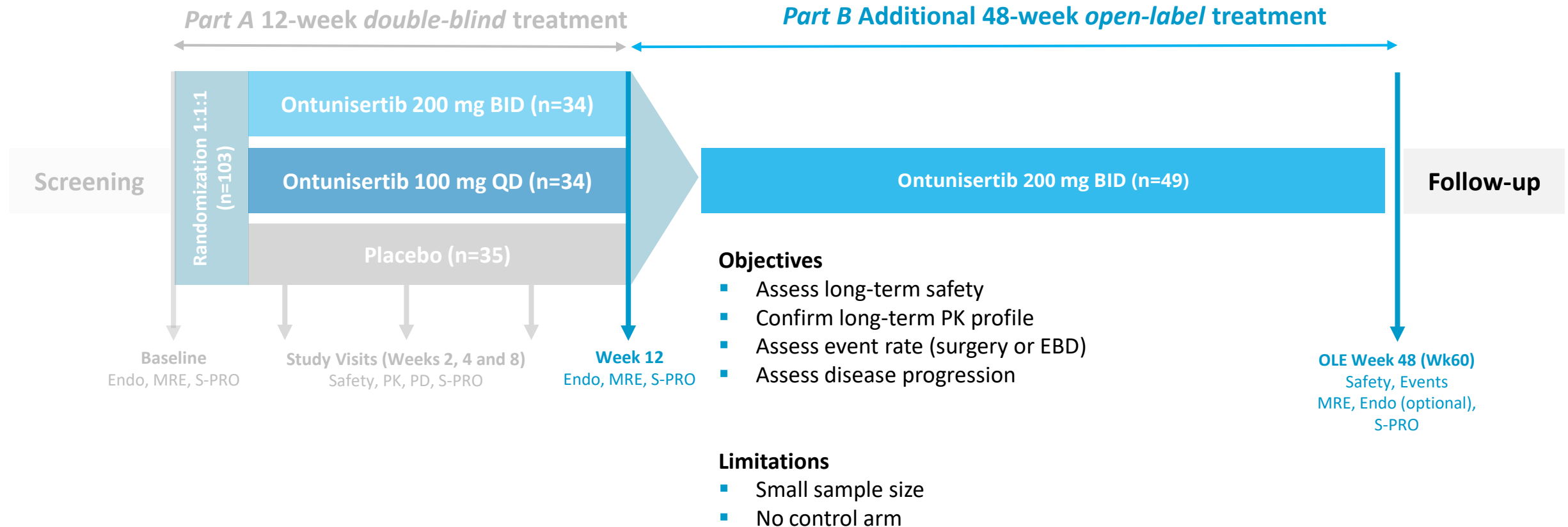
Sources: <sup>1</sup> Solitano 2026 doi: 10.1016/S2468-1253(26)00085-3; <sup>2</sup> Bettenworth 2024 doi: 10.1038/s41575-024-00935-y; <sup>3</sup> Internal data: FSCD patient interviews; <sup>4</sup> Danese 2018 doi: 10.1053/j.gastro.2018.03.032; <sup>5</sup> Whittle 2026 doi: 10.1007/s12325-026-03565-9; <sup>6</sup> Wetwittayakhang 2024 doi: 10.1177/17562848241272995; Notes: EBD = Endoscopic Balloon Dilation, QoL = Quality of Life

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# STENOVA: 2-part Phase 2a trial of ontunisertib in patients with FSCD

## TRIAL DESIGN



Note: BID, twice daily; Endo, endoscopy; MRE, Magnetic Resonance Enterography; PK, pharmacokinetics; PD, pharmacodynamics; PoC, proof-of-concept; PRO, Patient Reported Outcome; QD, once daily; SoC, Standard of care; S-PRO, Stricture-specific Patient Reported Outcome

# Majority of eligible patients rolled over into OLE

OLE initiated early 2025, with STENOVA *Part A* already underway

| Treatment disposition<br>n (%)   | Ontunisertib<br>200 mg BID<br>(N=16) | Ontunisertib<br>200 mg BID after<br>100 mg QD<br>(N=19) | Ontunisertib<br>200 mg BID after<br>Placebo<br>(N=14) | All Subjects<br>(N=49) |
|----------------------------------|--------------------------------------|---------------------------------------------------------|-------------------------------------------------------|------------------------|
| <b>Completed</b>                 | 14 (87.5)                            | 14 (73.7)                                               | 9 (64.3)                                              | 37 (75.5)              |
| <b>Discontinued</b>              | 2 (12.5)                             | 5 (26.3)                                                | 5 (35.7)                                              | 12 (24.5)              |
| Adverse event                    | 0                                    | 2 (10.5)                                                | 0                                                     | 2 (4.1)                |
| Lack of efficacy                 | 0                                    | 0                                                       | 3 (21.4)                                              | 3 (6.1)                |
| Lost to follow-up                | 0                                    | 1 (5.3)                                                 | 0                                                     | 1 (2.0)                |
| Noncompliance with study<br>drug | 1 (6.3)                              | 0                                                       | 0                                                     | 1 (2.0)                |
| Protocol deviation               | 0                                    | 0                                                       | 1 (7.1)                                               | 1 (2.0)                |
| Withdrawal by subject            | 1 (6.3)                              | 2 (10.5)                                                | 0                                                     | 3 (6.1)                |
| Other                            | 0                                    | 0                                                       | 1 (7.1)                                               | 1 (2.0)                |

- 49 patients rolled over into OLE
  - 94% of eligible STENOVA patients
- ~25% dropout rate
  - no discernible pattern

Note: BMI, body mass index; CDAI, Crohn's Disease Activity Index; CRP, C-reactive protein; FCP, fecal calprotectin; SD, standard deviation

# OLE patient population similar to overall STENOVA population

## Baseline characteristics

| Parameter                           | All OLE<br>Subjects<br>(N=49) | All Part A<br>Subjects<br>(N=103) |
|-------------------------------------|-------------------------------|-----------------------------------|
| Age (years), mean (SD)              | 42.0 (13.0)                   | 42.7 (13.8)                       |
| Female, n (%)                       | 13 (26.5)                     | 30 (29.1)                         |
| White, n (%)                        | 45 (91.8)                     | 93 (90.3)                         |
| BMI (kg/m <sup>2</sup> ), mean (SD) | 25.6 (5.2)                    | 26.4 (5.4)                        |
| Disease duration (years), mean (SD) | 15.7 (11.8)                   | 16.8 (11.6)                       |
| Ileocolonic disease, n (%)          | 30 (61.2)                     | 59 (57.8)                         |
| Intestinal resection, n (%)         | 19 (38.8)                     | 48 (46.6)                         |
| CDAI, mean (SD)                     | 151.2 (74.6)                  | 154.1 (83.1)                      |
| S-PRO severity, mean (SD)           | 7.1 (3.2)                     | 6.7 (3.4)                         |
| CRP (mg/L), mean (SD)               | 3.78 (3.69)                   | 4.07 (5.73)                       |
| FCP (mg/kg), mean (SD)              | 414.2 (512.3)                 | 442.6 (583.9)                     |
| SES-CD, mean (SD)                   | 6.6 (4.0)                     | 7.4 (4.4)                         |
| Prior biologics, n (%)              | 41 (83.7)                     | 88 (85.4)                         |
| Concomitant biologics, n (%)        | 37 (75.5)                     | 78 (75.7)                         |
| Concomitant thiopurine, n (%)       | 5 (10.2)                      | 10 (9.7)                          |
| Concomitant methotrexate, n (%)     | 0                             | 4 (3.9)                           |

- Predominantly male (>70%)
- Long disease history (>15 years)
- Approx. 40% prior surgery
- 75% on advanced biologics
- Mild luminal disease activity
- Approx. 40% isolated ileal disease

# Favorable long-term safety and tolerability profile

Low number of non-related SAEs in 48wk period

| Parameter                                    | Ontunisertib<br>200 mg BID<br>(N=16) | Ontunisertib<br>200mg BID<br>after 100 mg<br>QD<br>(N=19) | Ontunisertib<br>200 mg BID<br>after Placebo<br>(N=14) | All Subjects<br>(N=49) |
|----------------------------------------------|--------------------------------------|-----------------------------------------------------------|-------------------------------------------------------|------------------------|
| TEAE                                         | 9 (56.3)                             | 16 (84.2)                                                 | 10 (71.4)                                             | 35 (71.4)              |
| Serious TEAE                                 | 1 (6.3)                              | 2 (10.5)                                                  | 1 (7.1)                                               | 4 (8.2)                |
| Worst-case:                                  |                                      |                                                           |                                                       |                        |
| Moderate TEAE                                | 4 (25.0)                             | 8 (42.1)                                                  | 5 (35.7)                                              | 17 (34.7)              |
| Severe TEAE                                  | 1 (6.3)                              | 3 (15.8)                                                  | 1 (7.1)                                               | 5 (10.2)               |
| Life-threatening TEAE                        | 0                                    | 0                                                         | 0                                                     | 0                      |
| Fatal TEAE                                   | 0                                    | 0                                                         | 0                                                     | 0                      |
| Related TEAE                                 | 2 (12.5)                             | 0                                                         | 3 (21.4)                                              | 5 (10.2)               |
| Temporary treatment interruption due to TEAE | 2 (12.5)                             | 2 (10.5)                                                  | 2 (14.3)                                              | 6 (12.2)               |
| Permanent treatment interruption due to TEAE | 0                                    | 2 (10.5)                                                  | 0                                                     | 2 (4.1)                |
| Study discontinuation due to TEAE            | 0                                    | 0                                                         | 0                                                     | 0                      |

- 5 SAEs in 4 patients
- All considered not related or likely unrelated
  - Perforated appendicitis and small bowel obstruction
  - Crohn's Disease worsening
  - Wrist fracture
  - Ureterolithiasis

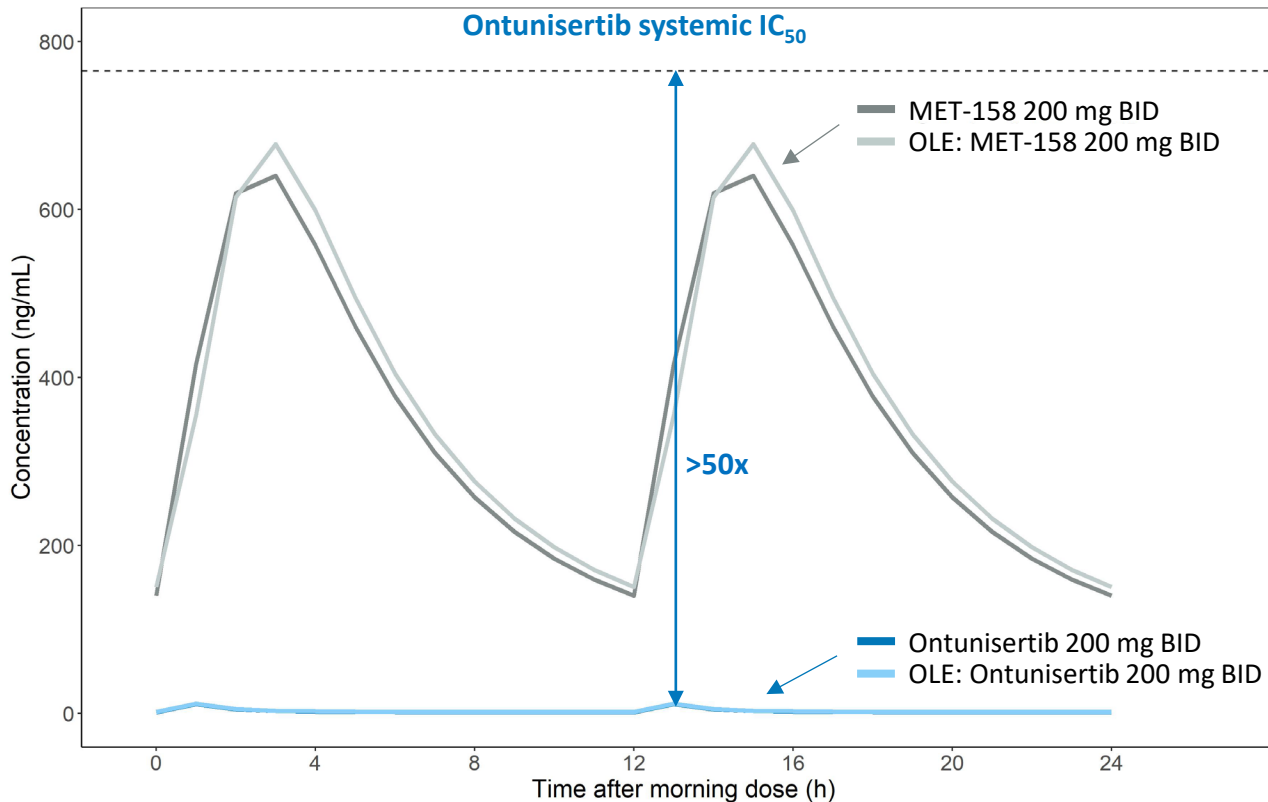
# OLE shows favorable long-term safety and tolerability profile of ontunisertib in FSCD up to 60 weeks

- Unremarkable AE profile in patients receiving ontunisertib 200 mg BID for up to 60 weeks
- No signals of cardiac injury, pro-inflammatory effects, or vasculitis
- No liver toxicity and no increase in GI-related AEs, in line with *Part A*
- Minimal number of SAEs, all unrelated or unlikely related
- DSMB did not identify any safety concerns based on available data throughout study

# Low systemic exposure of ontunisertib maintained over additional 48 weeks

Gut-restricted pharmacokinetics profile of ontunisertib sustained over time

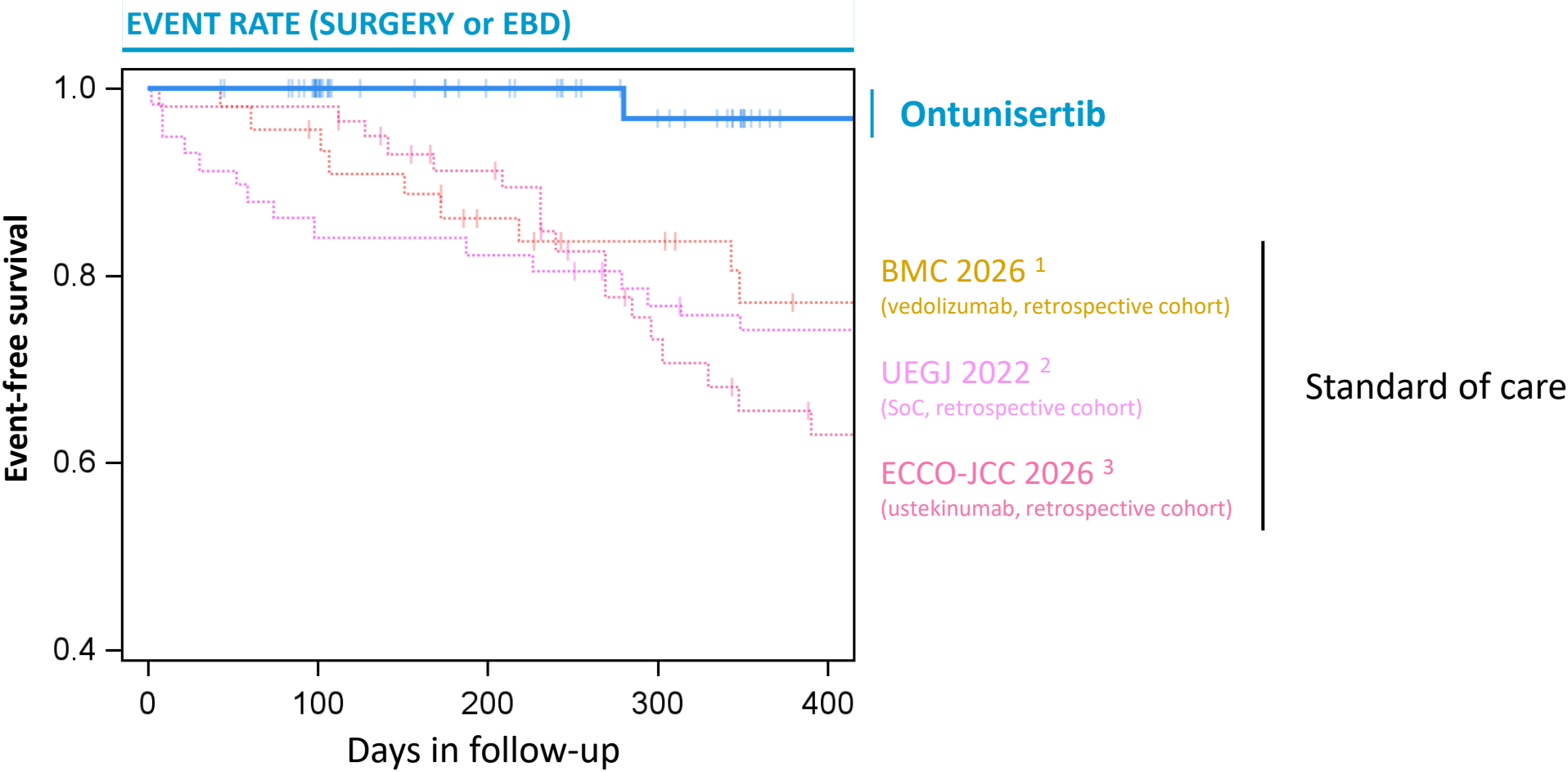
## LOW SYSTEMIC EXPOSURE (PLASMA) in STENOVA and OLE



Note: Figure shows GeoMean popPK model-derived profiles based on sparse PK sampling

- Ontunisertib and main inactive metabolite MET-158 popPK model-derived exposures and observed plasma concentrations in OLE (*Part B*) in line with STENOVA *Part A*
- Systemic ontunisertib exposure well below ontunisertib  $IC_{50}$  values

# Extended treatment with ontunisertib on top of SoC achieved low event rate (3%) in symptomatic FSCD patients



Sources: <sup>1</sup> Ouali 2026 = doi:10.1186/s12876-026-04815-4; <sup>2</sup> Ouali 2022 doi:10.1002/ueg2.12314; <sup>3</sup> Ouali 2026 = doi:10.1093/ecco-jcc/jjag038;  
Note: Figure shows published Kaplan-Meier curves (dotted) that were reproduced graphically from their source figures. Not based on head-to-head studies.

# Extended treatment with ontunisertib on top of SoC achieves low event rate (3%) in symptomatic FSCD patients

| Study                                                                    | 12-month event rate |
|--------------------------------------------------------------------------|---------------------|
| <b>STENOVA</b><br>(ontunisertib, <i>Part A + Part B, prospective</i> )   | 3%                  |
| <b>BMC 2026</b> <sup>1</sup><br>(vedolizumab, retrospective cohort)      | 23%                 |
| <b>UEGJ 2022</b> <sup>2</sup><br>(SoC, retrospective cohort)             | 26%                 |
| <b>ECCO-JCC 2026</b> <sup>3</sup><br>(ustekinumab, retrospective cohort) | 35%                 |

### STENOVA results

- Only 1 event (EBD) recorded (3%)
- No patients progressed to surgery for up to 60 weeks on ontunisertib treatment (0%)

### Comparable FSCD population

- Symptomatic FSCD patient population per CONSTRICT <sup>4</sup> criteria
- Comparable stricture morphology (length, BWT, dilatation) between STENOVA and published studies

Sources: <sup>1</sup> Ouali 2026 = doi:10.1186/s12876-026-04815-4; <sup>2</sup> Ouali 2022 doi:10.1002/ueg2.12314; <sup>3</sup> Ouali 2026 = doi:10.1093/ecco-jcc/jjag038; <sup>4</sup> Rieder 2018 doi: 10.1111/apt.14853  
Note: Not based on head-to-head studies. BWT = bowel wall thickness.

# Events have a high impact on patients and healthcare systems

Bowel damage leads to events (surgery), poor quality of life and increased healthcare costs

FSCD-related events have high burden on patient quality of life <sup>1</sup>

**5-8x**

more likely to undergo surgery vs  
'uncomplicated Crohn's Disease'

**2-4x**

more inpatient admissions vs  
'uncomplicated Crohn's Disease'

**2x**

longer inpatient stays vs  
'uncomplicated Crohn's Disease'

**2-3x**

more endoscopies vs  
'uncomplicated Crohn's Disease'

And translate into high healthcare costs <sup>1</sup>

**>\$80K**

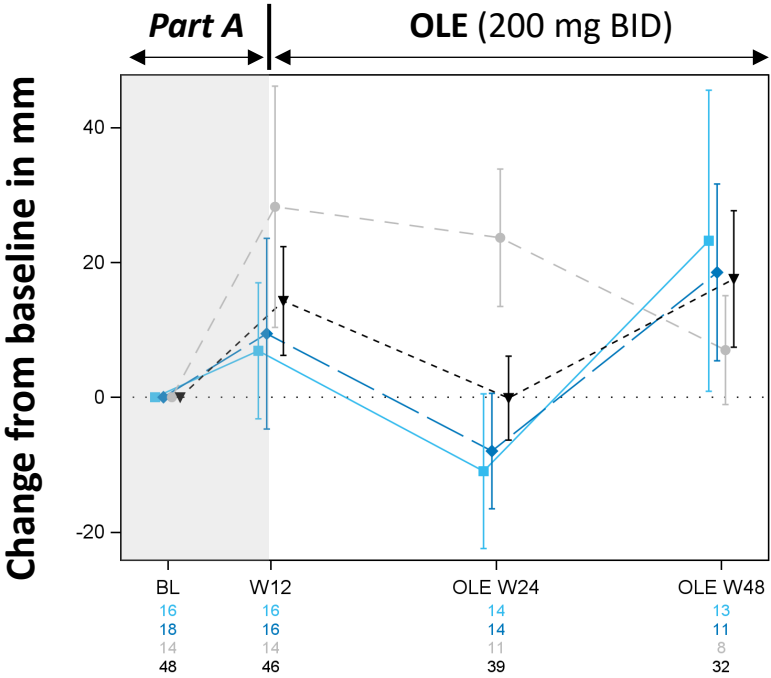
**Higher yearly healthcare costs  
vs uncomplicated CD**

Driven by medical<sup>2</sup> and  
medication costs

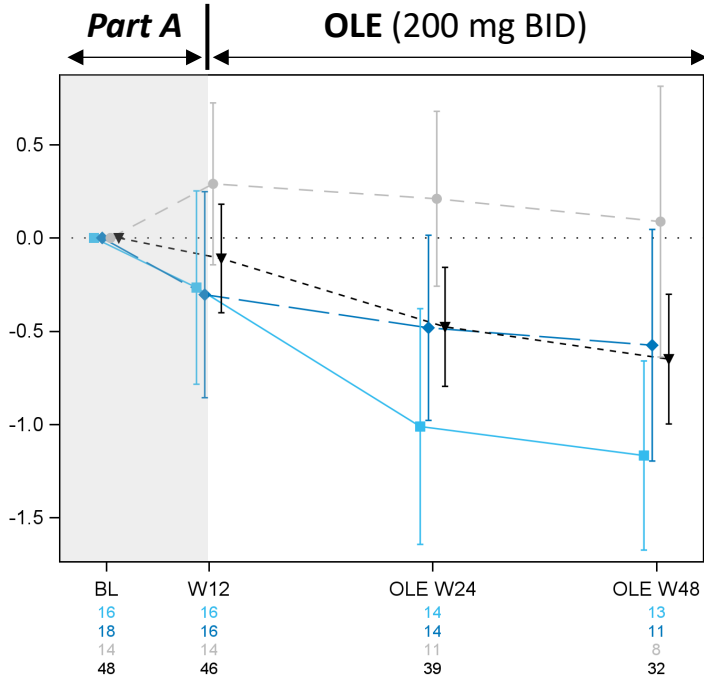
Sources: <sup>1</sup> Study by Boehringer Ingelheim, Fan et al. 2023 doi: 10.18553/jmcp.2023.29.4.400; <sup>2</sup> Medical costs are inpatient visits, outpatient visits, emergency department visits including CD-related procedures and surgeries

# MRE data suggest stricture stabilization & possible improvement in OLE

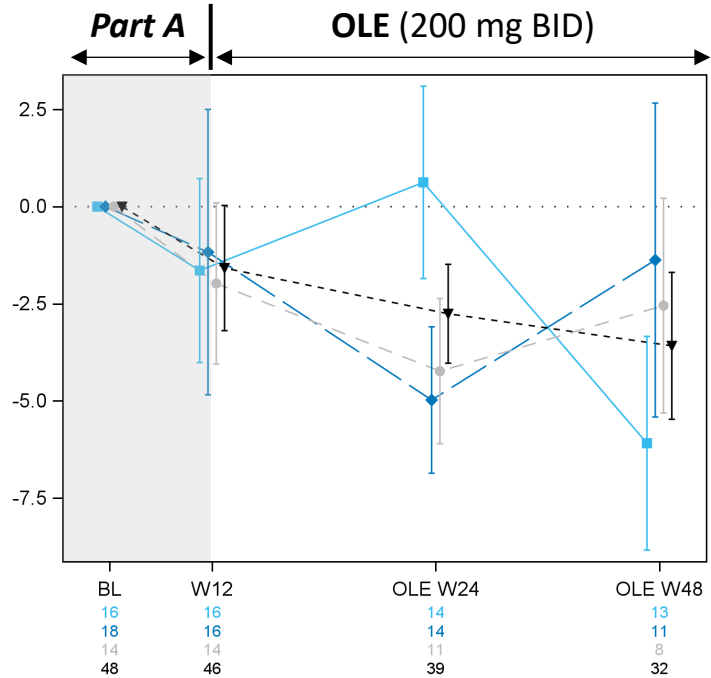
STRICTURE LENGTH



BOWEL WALL THICKNESS

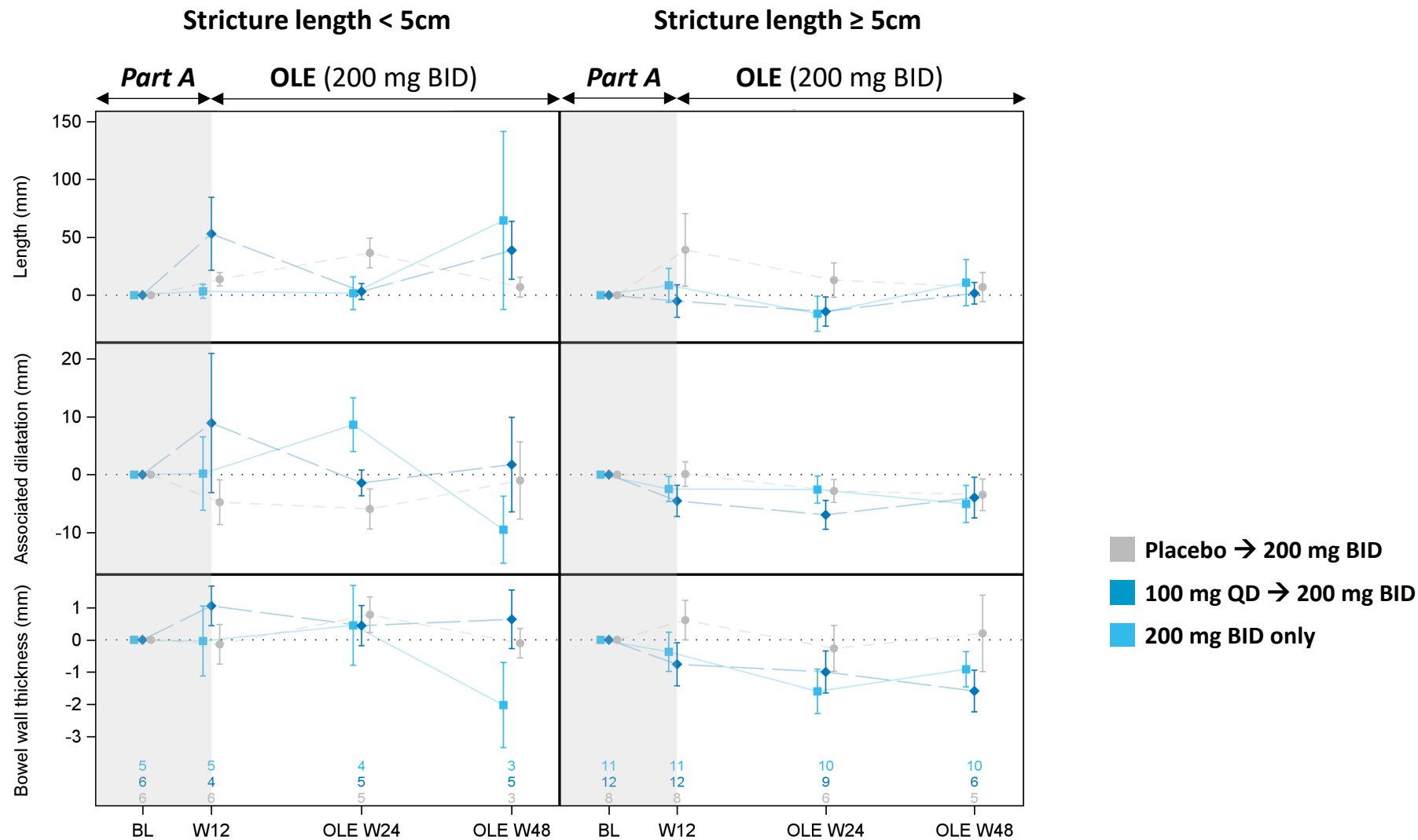


ASSOCIATED DILATATION DIAMETER



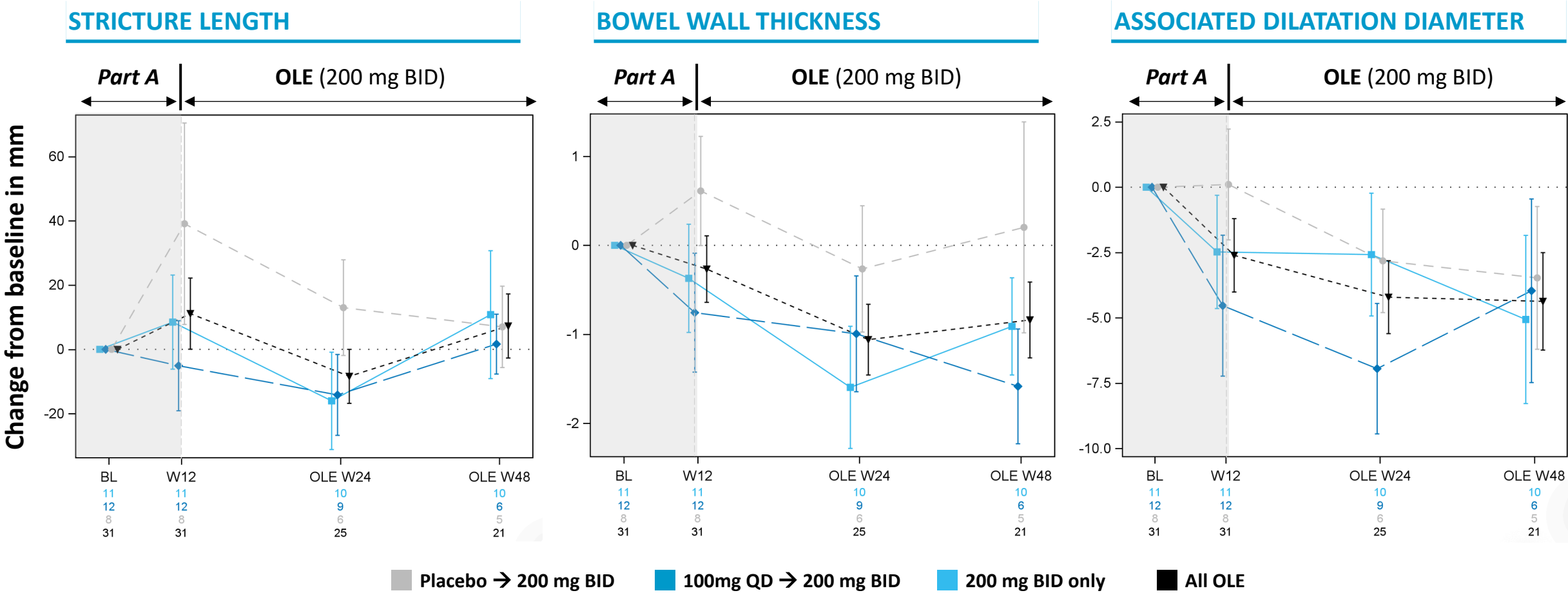
■ Placebo → 200 mg BID    ■ 100 mg QD → 200 mg BID    ■ 200 mg BID only    ■ All OLE

# MRE results over *Parts A & Part B*: variability for short strictures (<5cm) vs consistent pattern for longer strictures (≥5cm)



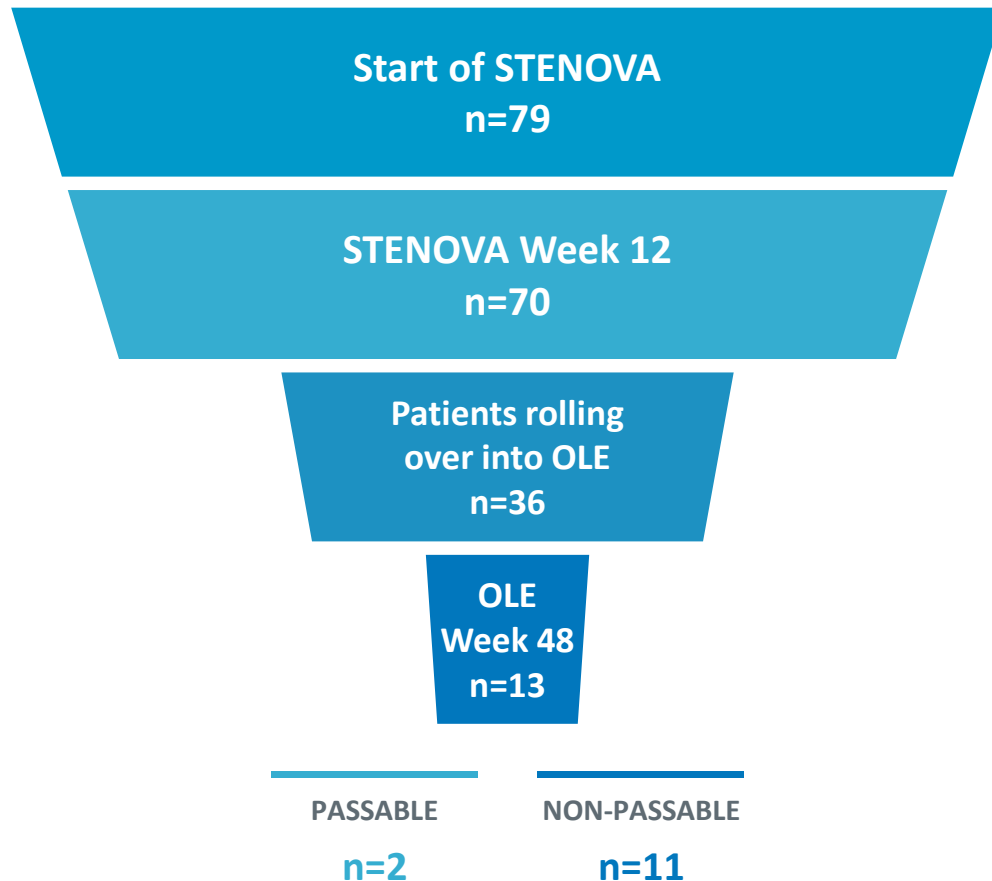
# Lower variability observed in patients with longer strictures at baseline

Subgroup: stricture length  $\geq 5\text{cm}$  at baseline



# Endoscopic passability – Limited dataset precludes interpretation

Number of endoscopies available in patients with non-passable strictures at baseline

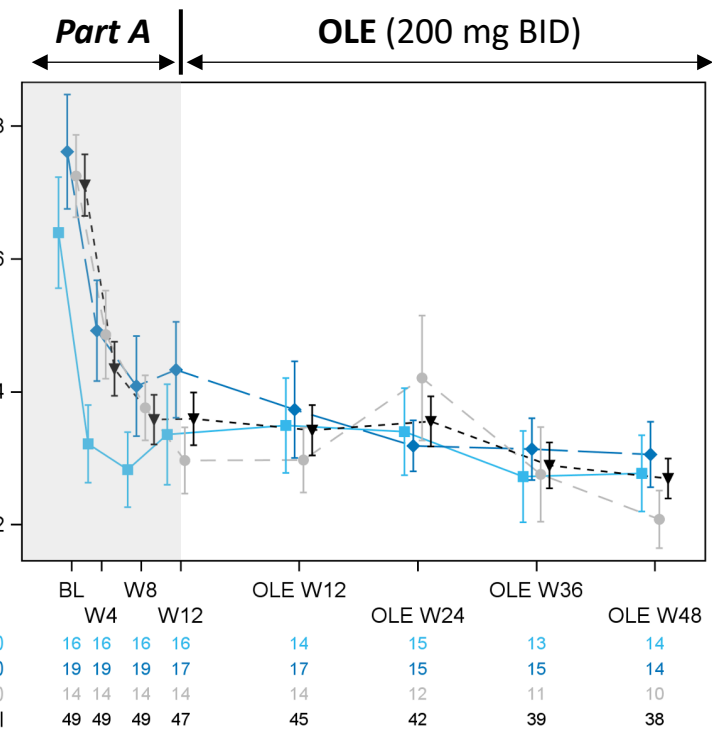


- OLE study limitations
  - Endoscopy elective at Week 48 in OLE
  - Absence of control arm in open-label part
- Limited data for patients with non-passable stricture at baseline
  - Assessment of only 13 patients at Week 48

**NOV-ERA Phase 2b designed to robustly assess passability (mandatory endoscopy; powered study; larger sample size)**

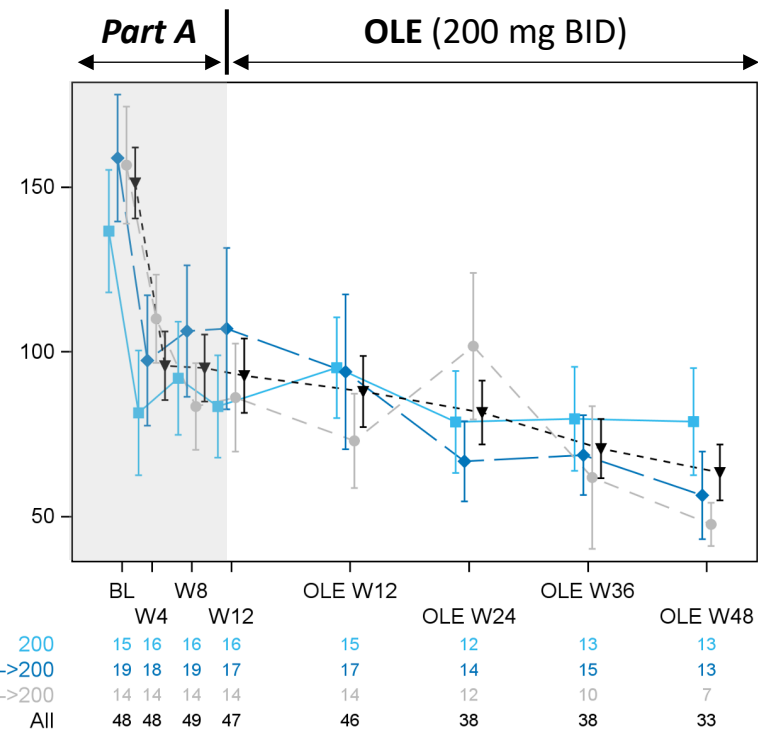
# Sustained symptomatic control over 48-week treatment period

S-PRO SEVERITY SCORE



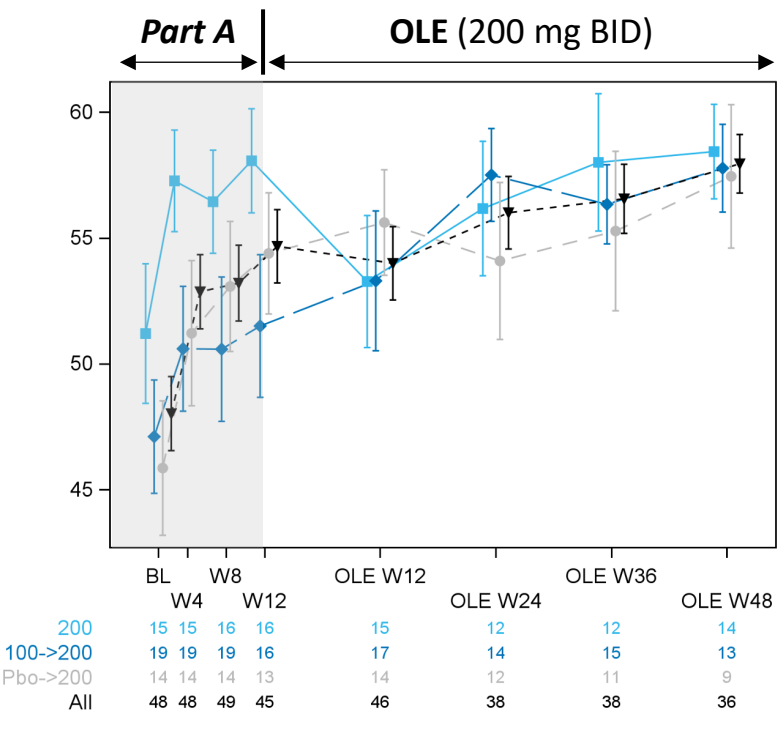
Minimal obstructive symptoms

CDAI TOTAL SCORE



Clinical remission  
(97% in remission at W48)

SHORT IBD-Q (QUALITY OF LIFE)



Improved quality of life

Placebo → 200mg BID    100mg QD → 200mg BID    200mg BID only    All OLE

# STENOVA open-label extension study – key takeaways

- Generally favorable long-term safety and tolerability profile
- Confirmed gut-restricted PK profile
- Very low annualized FSCD-related event rate (surgery/EBD) of 3%
- Sustained disease control:
  - Low symptoms and disease activity scores (S-PRO, CDAI, IBD-Q)
  - Radiological stabilization of strictures (MRE)

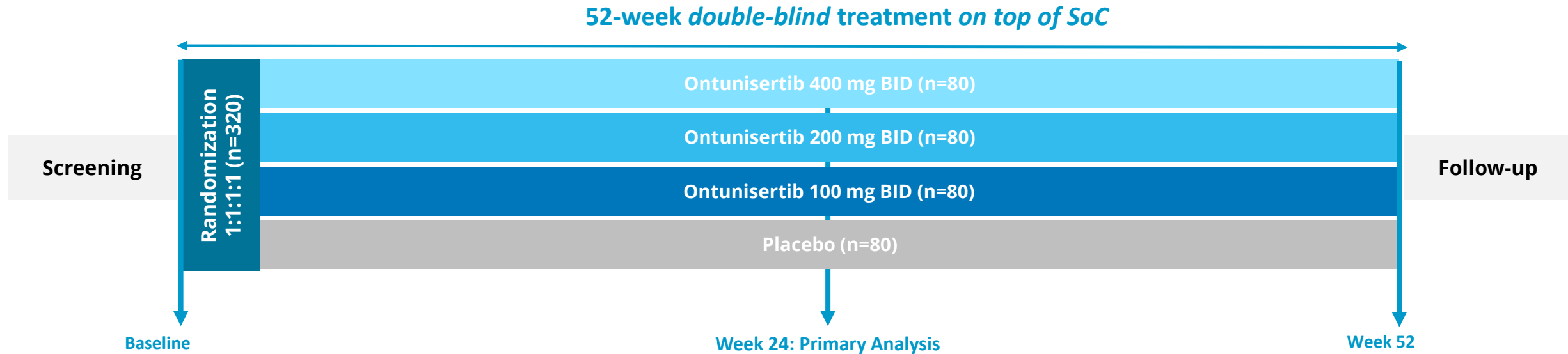
**OLE results support further development of ontunisertib in FSCD (NOV-ERA)  
and potential expansion to additional IBD indications**

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# NOV-ERA, a global Phase 2b study to confirm efficacy of ontunisertib in FSCD

Phase 2b to validate and inform selection of registrational endpoints



## Population:

- Symptomatic FSCD patients
- At least 1 non-passable ileal stricture (central endoscopy)
- Confirmed fibrotic stricture as per STAR criteria (central MRE)
- Stable anti-inflammatory background therapy

## Primary endpoint:

Proportion of participants achieving endoscopic passability at Week 24

## Secondary endpoints include:

- Endoscopic response and remission (SES-CD)
- Radiologic response (MRE)
- Event rate (surgery, EBD, FSCD-related hospitalization)
- Symptomatic improvement (S-PRO 2.0)
- Safety

Note: EBD, endoscopic balloon dilation

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# Thank you!

*Contact: [sofie.vangijssel@agomab.com](mailto:sofie.vangijssel@agomab.com)*

**AGOMAB**

The background of the slide features a dark blue gradient with a subtle pattern of glowing green and blue particles. Overlaid on the right side is a semi-transparent silhouette of a human figure from the waist up, facing away from the viewer. The silhouette is filled with a complex, glowing molecular structure composed of interconnected hexagons and lines, resembling a honeycomb or crystalline lattice. This structure is more prominent on the back and shoulders, fading towards the arms and head.