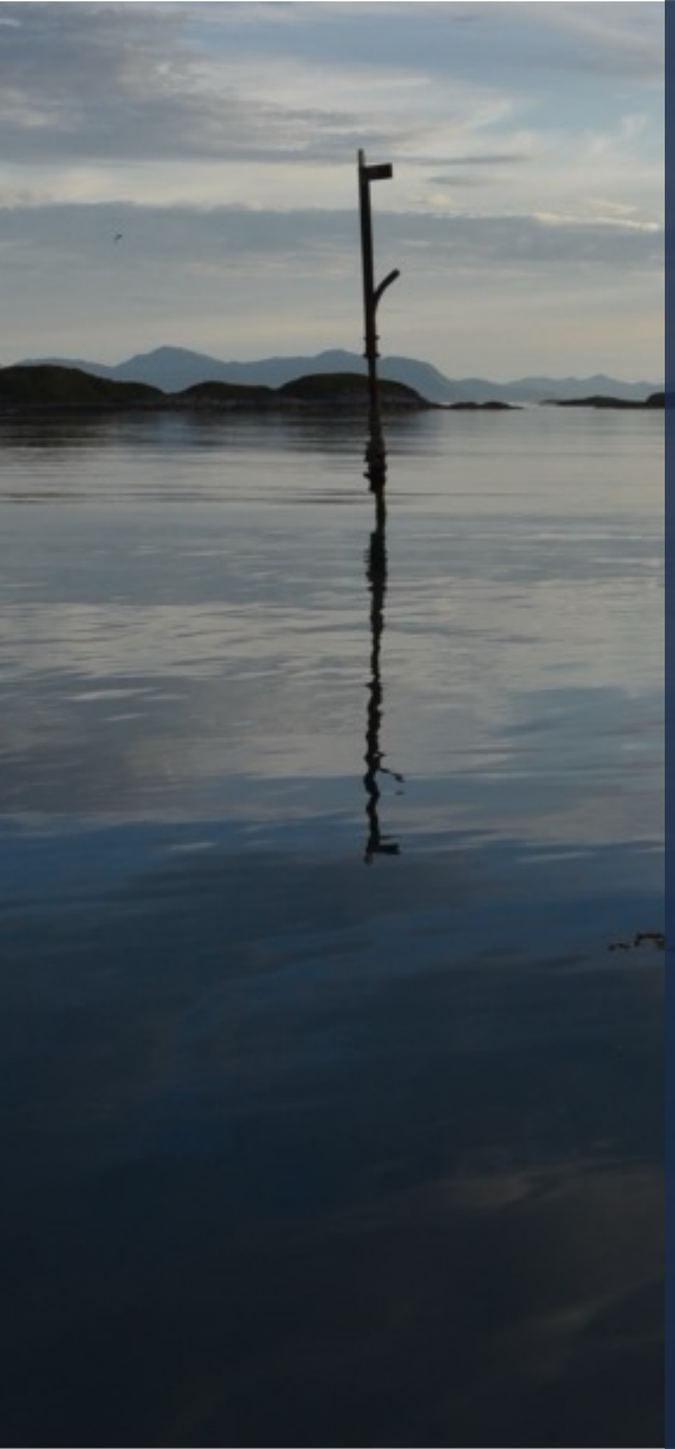


Arctic Bioscience AS

HeROPA study

HRO350 in mild-to-moderate psoriasis

Data read-out
July 2025

EU CT number: 2022-501850-12-00
EudraCT number: 2021-003684-96
ClinicalTrials.gov ID: NCT06125808

HeROPA

Foundation for commercial discussions established, subgroups show statistical significance

Key findings

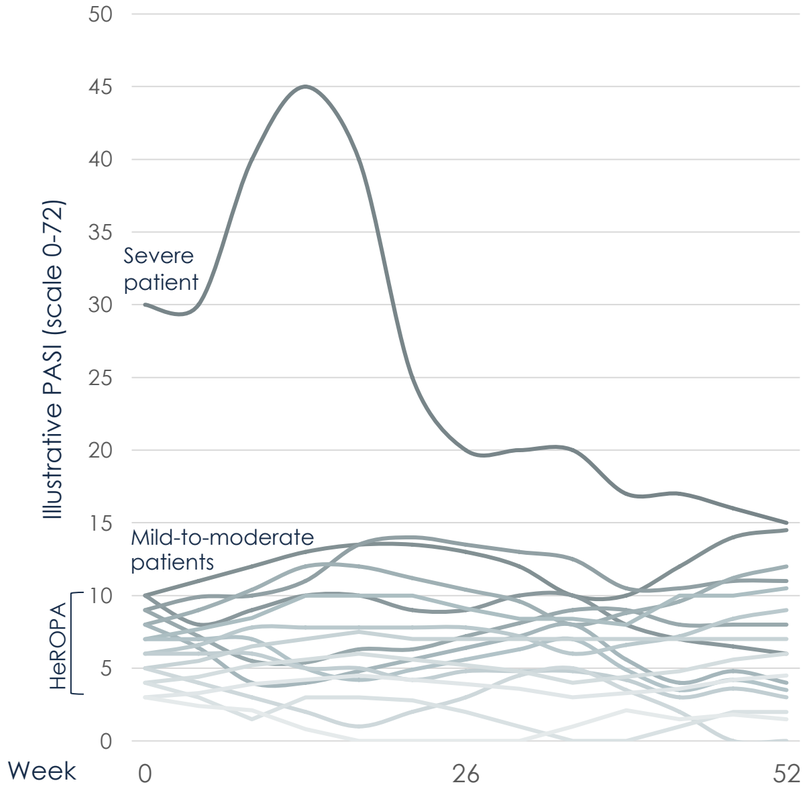
- Primary endpoint PASI50 difficult to reach due high placebo rate; endpoint sensitive to disease fluctuations (as reported in October 2024)
- Stricter endpoints like PGA 0/1 on per protocol population approaching significance ($p = 0.07$)
- Relevant subgroups show statistical significance ($p < 0.05$)
- Robust safety data with no serious concerns observed in the period and HRO350 is well tolerated by the patients
- Combination of statistical significance in subgroups, responder analysis and robust safety data as base for planning future phase III and clinical development
- Promising results going into further partner discussion this fall

HeROPA

Primary endpoint PASI50 difficult to measure in mild population

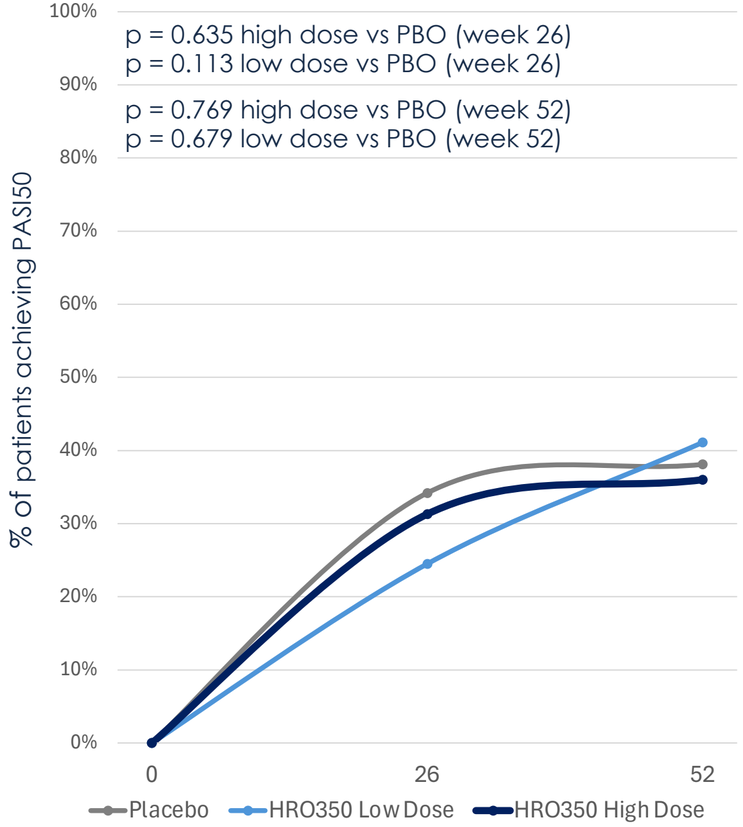
Natural disease fluctuations and limited precision on lower end of PASI scale makes it hard to show differences in PASI50 between groups for patients with mild-to-moderate psoriasis

Illustration of hypothetical PASI fluctuations



For visual illustration only: Fluctuations of PASI50 magnitude from baseline in a mild-to-moderate population (PASI 3-10) who naturally experience seasonal variation and episodes of spontaneous remission or worsening, versus a severe patient with PASI 30 at baseline achieving PASI50 (biologics trial).

PASI50 (PP population)



Comments

- **PASI50** compared between HRO350 and placebo at 6 months was the primary endpoint, which was not met
- **Efficacy of HRO350** observed as assumed in protocol for patients who completed 1 year of treatment
- **Placebo response-rate** was much higher than predicted
- **PASI scale** has less precision in mild disease[1]

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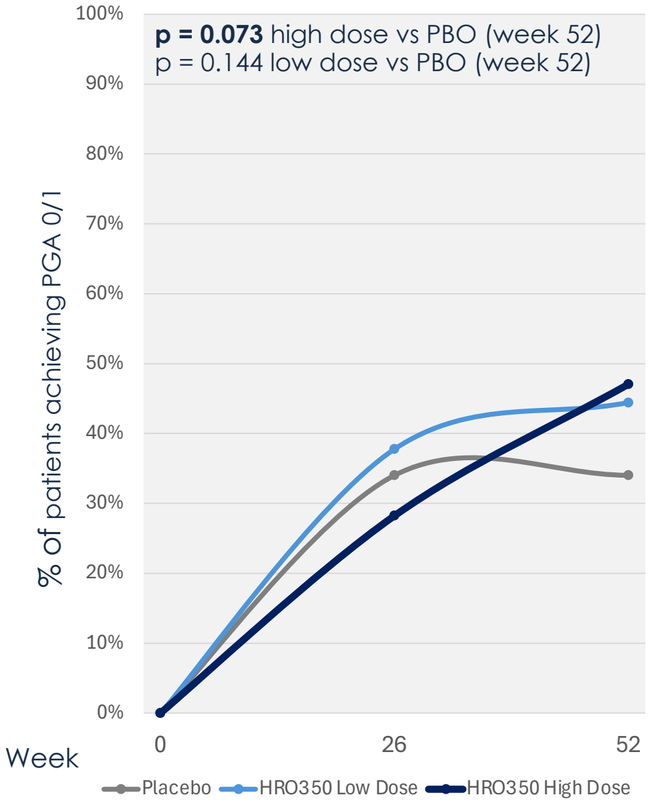
PASI50: The proportion of patients with ≥50% reduction in Psoriasis Area and Severity Index (PASI, scale from 0-72) from baseline. PP: Per Protocol Population for PASI. Week 52 n = 273. Data as observed. ITT: Intention to treat. N = 521, data not shown. p = 0.472 high dose, p = 0.626 low dose (week 52)

1) Papp KA et al., Dermatol Ther (Heidelb) (2021) 11:1079–1083. https://doi.org/10.1007/s13555-021-00572-2

Stricter endpoint differentiates better: PGA 0/1 (clear or almost clear)

Key secondary endpoint: Physician's Global Assessment (PGA 0/1) is easier to measure and more difficult to achieve

Patients achieving PGA 0/1 (PP population)



Comments

- Nearly half of patients treated with HRO350 achieved clear-or-almost clear skin after 52 weeks
- PGA 0/1 is a much harder endpoint to reach than PASI50
- 47% of patients in the high dose arm achieved a PGA 0/1 at week 52, versus 34% in the placebo group (p = 0.073)
- In the previous Haukeland study[1] 40% of patients achieved PGA 0/1 after 65 weeks
- All patients had PGA scores ≥ 2 and ≤ 4 at inclusion

PP: Per Protocol population for sPGA for patients who completed 52 weeks: n = 272. Data as observed. ITT: Intention to Treat population for sPGA: N = 521. (Non-Responder Imputation analysis not shown. p = 0.490 for high dose vs placebo and p = 0.608 for low dose vs placebo)

Static PGA (sPGA) measures physician's impression at a single time point. Static form is standard due to reliability

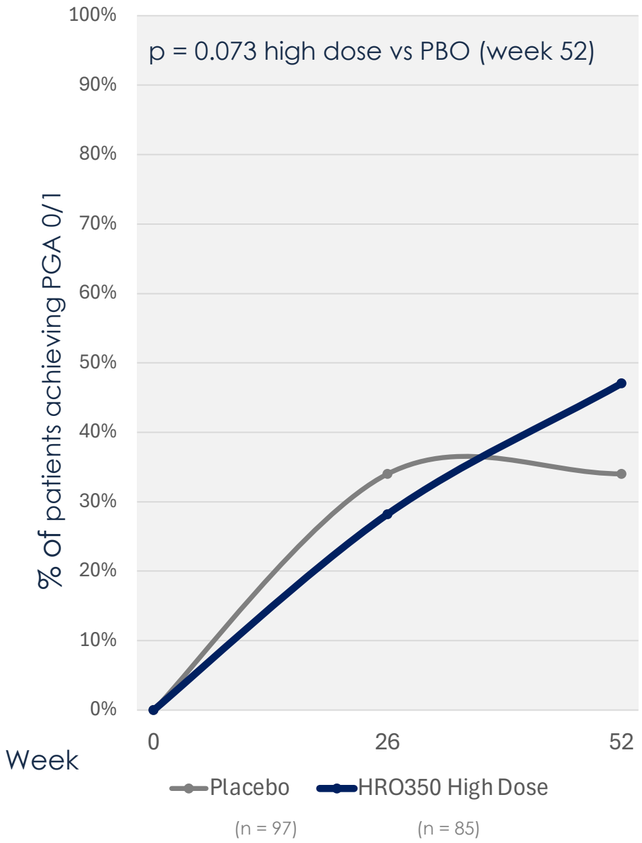
1. Tveit KS et al. Long Term Efficacy and Safety of Herring Roe Oil in the Treatment of Psoriasis, a 39-week Open-label Extension Study. International Journal of Clinical and Experimental Medical Sciences. Vol. 7, No. 1, 2021, pp. 13-20. doi: 10.11648/j.ijcems.20210701.13. 2) 3) Stein Gold L, et al. Efficacy and safety of apremilast in patients with mild-to-moderate plaque psoriasis: Results of a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. J Am Acad Dermatol. 2022 Jan;86(1):77-85. doi: 10.1016/j.jaad.2021.07.040. PMID: 34343599..

HeROPA

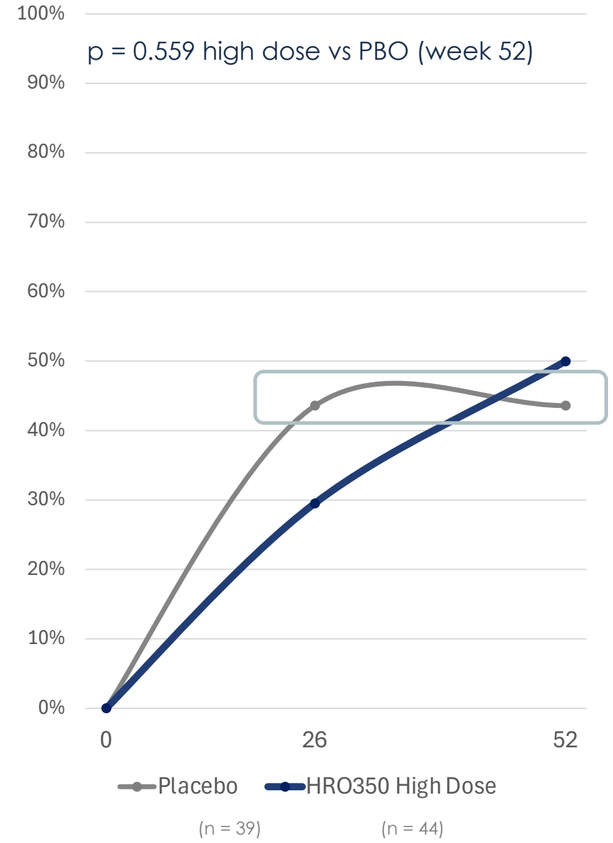
Higher placebo rate in patients with milder disease at baseline

Subanalysis identified differentiators on placebo response: Baseline severity

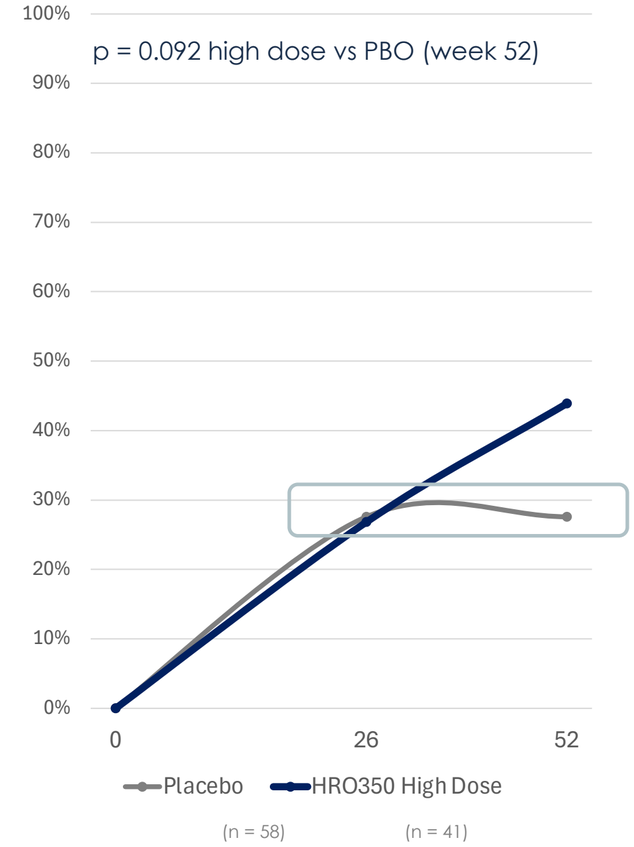
All Patients achieving PGA 0/1 (PP)



PASI < 6 at baseline (PP)



PASI ≥ 6 at baseline (PP)



Comments

- Post-hoc analysis: Placebo response is higher in patients with PASI < 6 at baseline
- Patients with PASI ≥ 6 and < 6 respond similarly in the high dose arm

Post-hoc analysis on the Per Protocol (PP) Population for sPGA. Week 52 n=272. Data as observed. ITT: Intention to treat. N = 521 all time points. (Non-Responder Imputation analysis not shown. p = 0.490, p = 0.995, and p = 0.391 for high dose vs placebo)

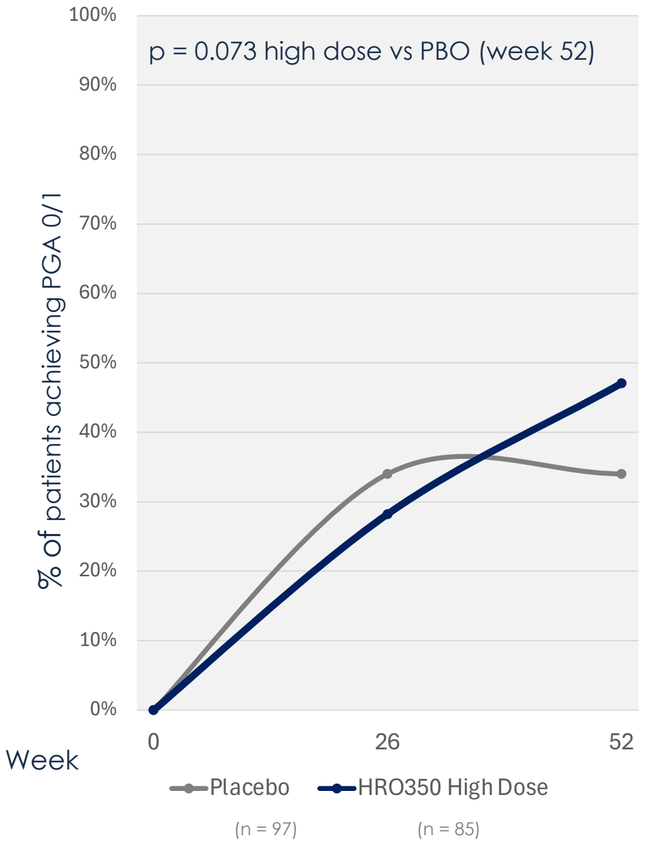
Static PGA measures physician's impression at a single time point. Static form is standard due to reliability.

HeROPA

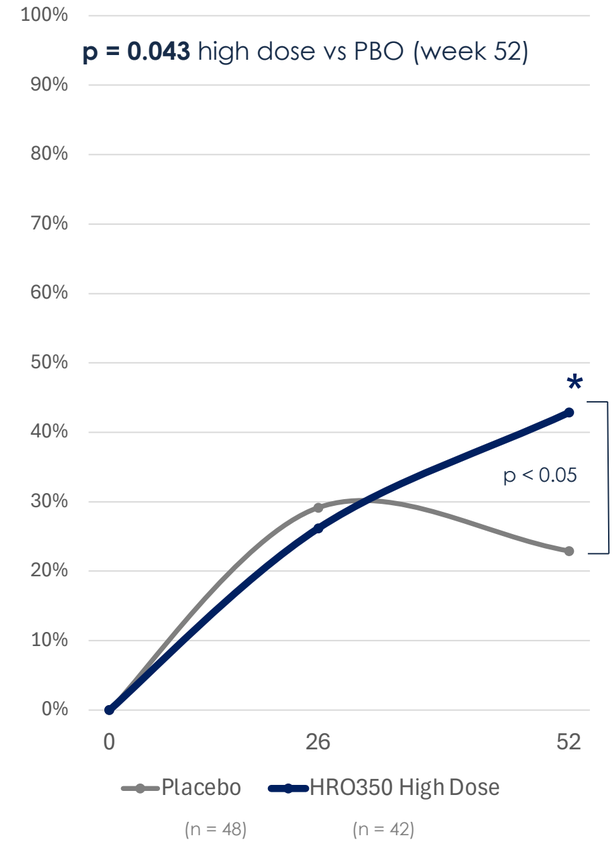
Lower placebo rate in patients ≥ 50 years

Subanalysis identified statistically significant subgroup: Impact of age

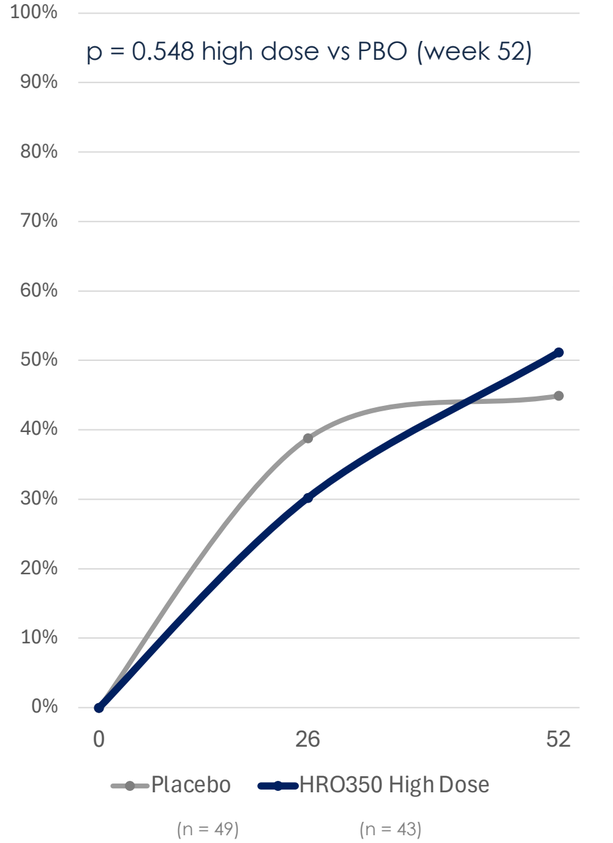
All Patients achieving PGA 0/1 (PP)



Patients ≥ 50 years (PP)



Patients < 50 years (PP)



Comments

- Post-hoc analysis: Lower placebo rates ≥ median age(≥ 50 years)
- Younger age with shorter duration of psoriatic disease may increase chance of spontaneous improvement in the placebo group
- Patients of all ages respond similarly in the high dose arm

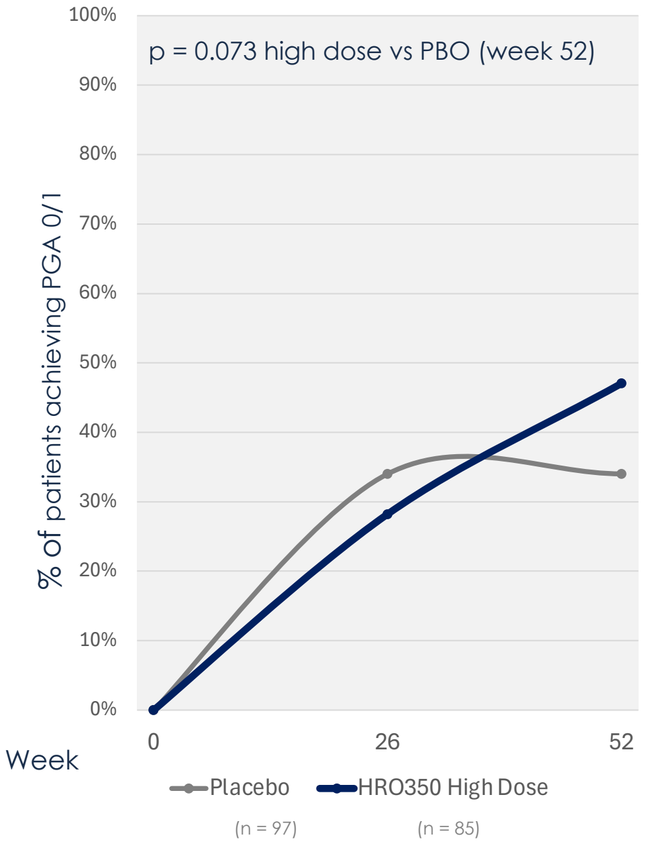
Post-hoc analysis on the Per Protocol (PP) Population for sPGA. Week 52 n = 272. Data as observed. ITT: Intention to treat. N = 521 all time points. (Non-Responder Imputation analysis not shown. p = 0.490, p = 0.254, and p = 0.946 for high dose vs placebo)
Static PGA measures physician's impression at a single time point. Static form is standard due to reliability

HeROPA

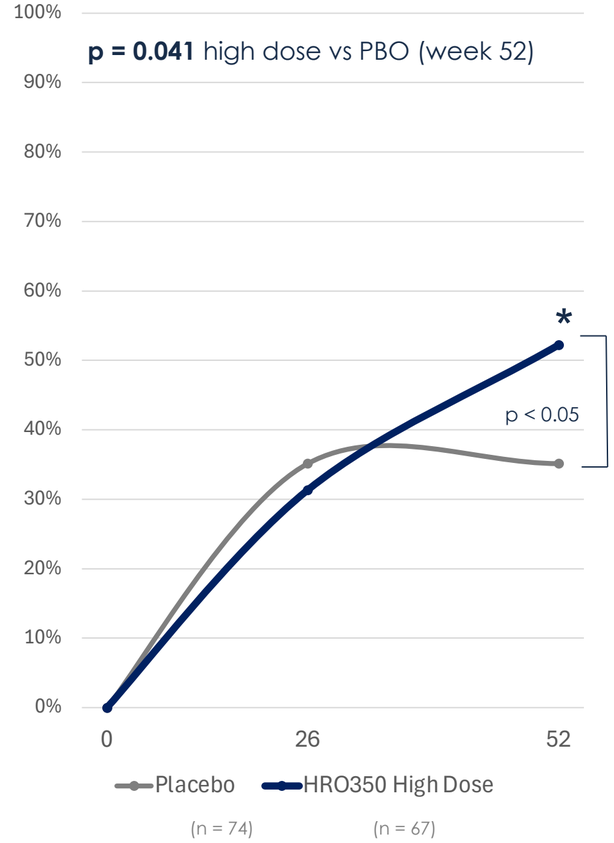
Higher response rates in active arm for patients with weight ≤ 98 kgs

Subanalysis identified statistically significant subgroup: Impact of weight

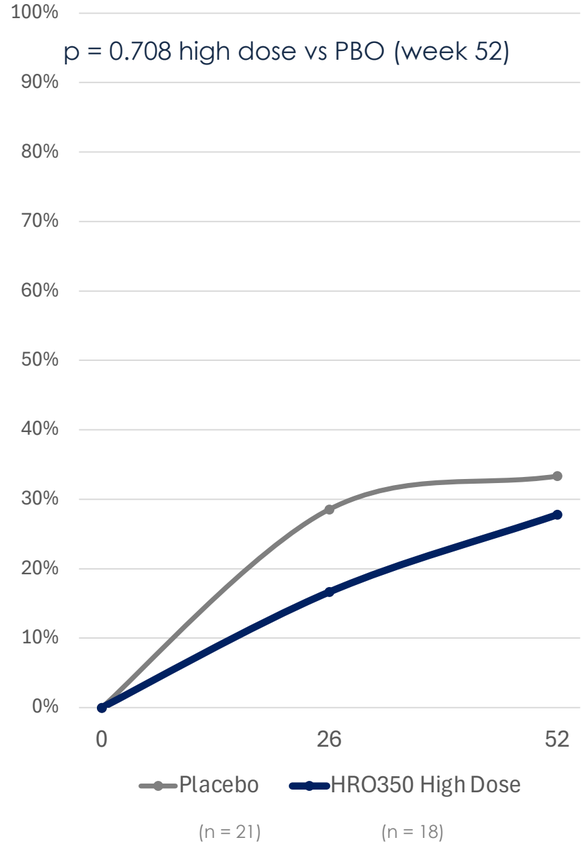
All Patients achieving PGA 0/1 (PP)



Weight ≤ 98 kg (PP)



Weight > 98 kg (PP)



Comments

- Post-hoc analysis showed that more patients in lower three weight quartiles (patients weighing ≤ 98 kgs) in PP achieved a PGA 0/1 at week 52 than patients in the highest weight quartile

Post-hoc analysis on the Per Protocol (PP) Population for sPGA. Week 52 n = 272. Data as observed. ITT: Intention to treat. N = 521 all time points. (Non-Responder Imputation analysis not shown. p = 0.490, p = 0.469, and p = 0.868 for high dose vs placebo). Missing weight: n = 2 PBO
Static PGA measures physician's impression at a single time point. Static form is standard due to reliability

HeROPA

Robust safety on HRO350

Well tolerated with no serious safety concerns

HRO350 safety from HeROPA patients (N = 521) treated for up to 1 year

No Serious Safety Concerns
No drug-related Serious Adverse Events (SAEs) or Suspected Unexpected Serious Adverse Reactions (SUSARs) were reported

Independent Oversight Confirmed Safety
Periodic reviews by the independent Data Monitoring Committee (DMC) raised no safety concerns throughout the trial

Well Tolerated Over 1 Year
HRO350 demonstrates a favorable safety profile throughout 12 months of treatment and 2 months post-treatment follow-up
Few drug-related adverse events (AEs) and low drop-outs due to drug-related AEs
Adverse events observed were consistent with expectations and those seen in the Haukeland study

Regulatory-Ready Documentation
Full safety data analysis, including frequency tables and SAE narratives will be detailed in the Clinical Study Report

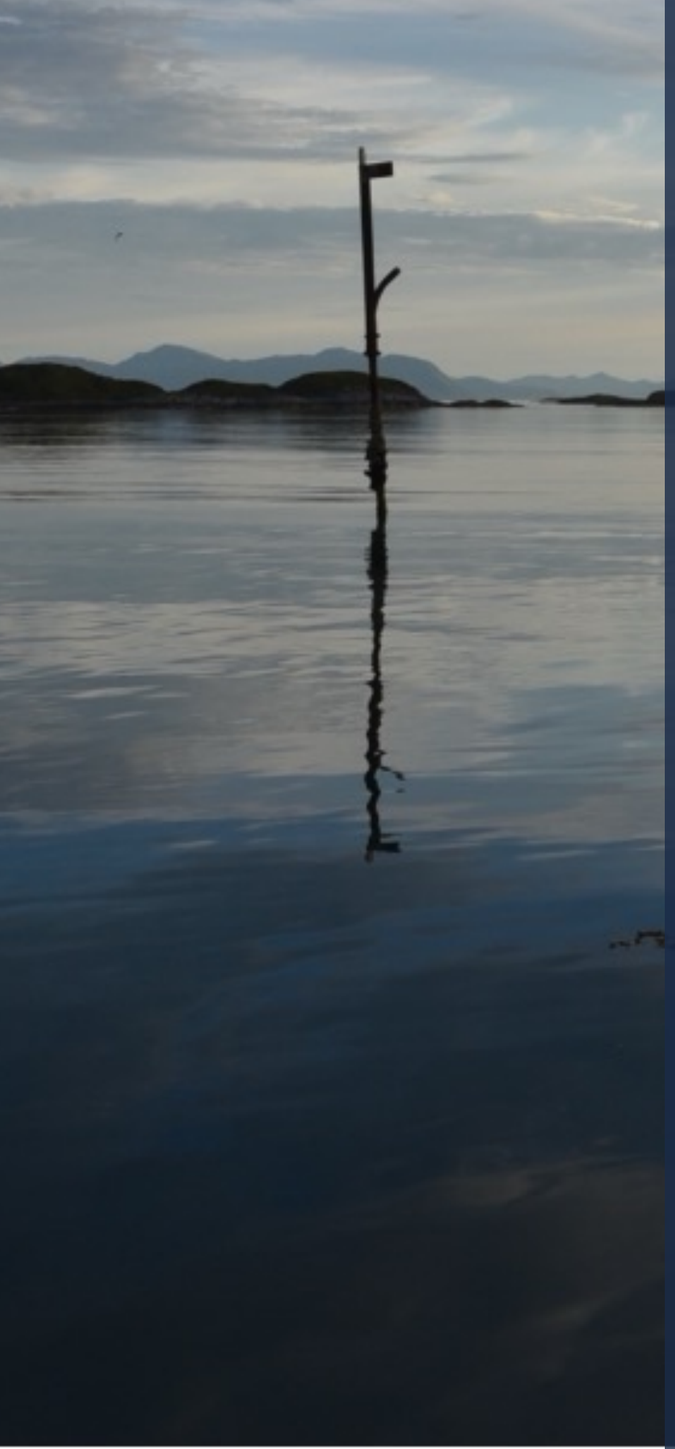
HeROPA

Plan going forward

- Nutra business is growing strongly (~30 % annually)
- We strongly believe there is a major market potential for HRO350 in mild-to-moderate psoriasis
- Arctic Bioscience will seek partnerships for further development of HRO350 with a potential Phase III clinical program


ARCTIC
BIOSCIENCE
Q&A
HeROPA

Appendix



ARCTIC BIOSCIENCE

HRO350 in mild-to-moderate psoriasis

Market and value proposition

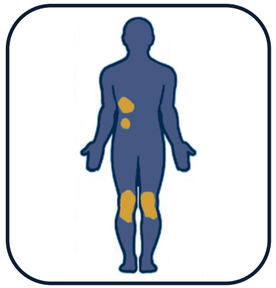
HRO350 Strategic Positioning: mild-to-moderate psoriasis

~18.7M mild-to-moderate patients in the U.S. and EU5

- **~22.5M total** psoriasis patients across severity types (~10.7 U.S. and ~11.8 EU5)
- **~80% of U.S.** patients and **~90% of EU5** patients have **mild-to-moderate** psoriasis
- **HRO350 is targeting a total addressable market of ~18.7M mild-to-moderate psoriasis patients**

ARCTIC BIOSCIENCE

Split of Disease Severity

Mild-to-Moderate		Moderate-to-Severe and Severe
In the U.S., 50% of patients (~5M) In the EU5, 66% of patients (~7.8M)	In the U.S., 30% of patients (~3M) In the EU5, 25% of patients (~2.9M)	In the U.S., 20% of patients (~2M) In the EU5, 11% of patients (~1.3M)
		
PASI < 3/5*	3/5* < PASI < 10	PASI > 10

*Split between mild and moderate patients varies in the literature.

Sources: HRO350 Commercial Opportunity Assessment in Psoriasis, IQVIA; WHO Global Report on Psoriasis; Rendon. Int J Mol Sci. 2019 Mar; 20(6): 1475; UpToDate; American Academy of Dermatology Association; Papp. Dermatol Ther. 11:1053; 2021; National Psoriasis Foundation; Evaluate Pharma 2022 Psoriasis Market Size, November 2022 Analysis.

Paediatric indication for HRO350: upside potential

Potential first-line treatment for children with mild-to-moderate psoriasis

Paediatric Investigation Plan (PIP) agreed with the Paedatric Committee* of the EMA

- Drug development program for children <18 years of age with psoriasis
- Component of the regulatory drug development journey for HRO350
- Prerequisite for filing for marketing authorization (MA) for new medicines in Europe

Limited approved products in standards of care High unmet medical need

- A future paediatric indication would increase patient population who could have benefit from HRO350
- 1% of children under age 18 suffer from psoriasis
- Plan for expanded indication for HRO350
- Limited treatment options – potential first line treatment for mild-to-moderate psoriasis in children
- Unmet need for oral treatments – only apremilast currently in clinical trials for mild-to-moderate pediatric psoriasis (> 6 yrs) in the US

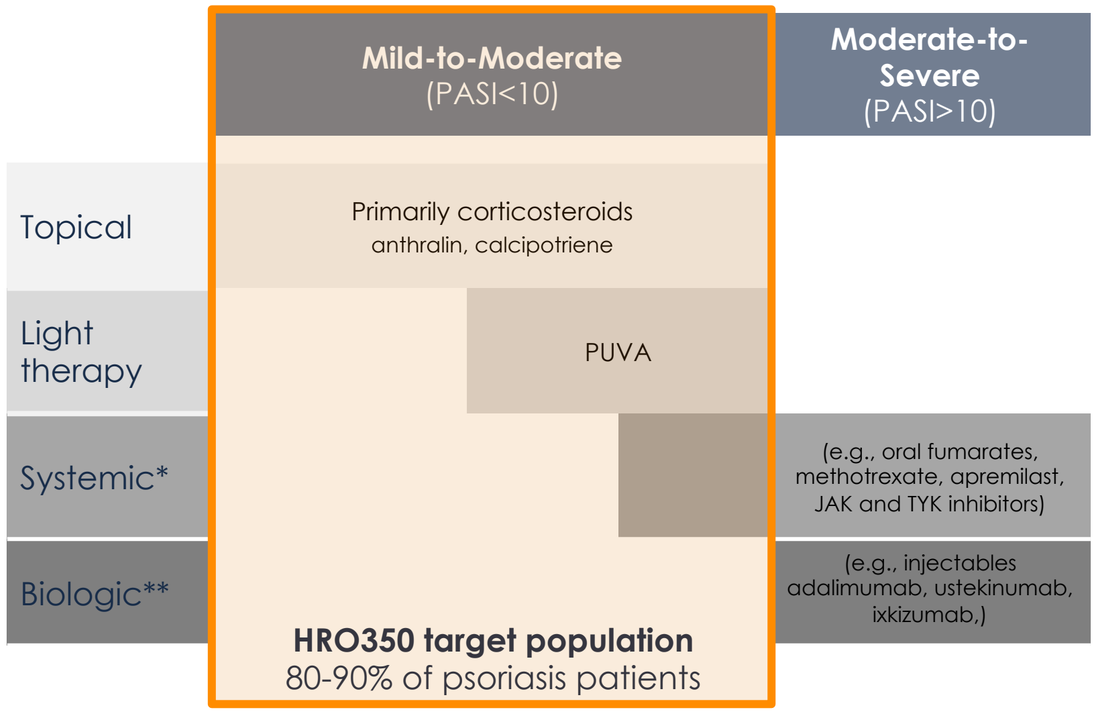
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

*The Paediatric Committee of the EMA provides opinions on the quality, safety and efficacy of a medicine for use in the paediatric population

References: Augustin M, Glaeske G, Radtke MA, Christophers E, Reich K, Schäfer I. Epidemiology and comorbidity of psoriasis in children. Br J Dermatol. 2010 Mar;162(3):633-6. doi: 10.1111/j.1365-2133.2009.09593.x. Epub 2009 Nov 18. PMID: 19922529; Haulrig MB, Zachariae C, Skov L. Off-Label Treatments for Pediatric Psoriasis: Lessons for the Clinic. Psoriasis (Auckl). 2021 Feb 11;11:1-20. doi: 10.2147/PTT.S268462. PMID: 33604269; PMCID: PMC7886293.; Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):574]. J Am Acad Dermatol. 2020;82(1):161-201.

HRO350 could meet an unmet medical need for patients with non-severe psoriasis

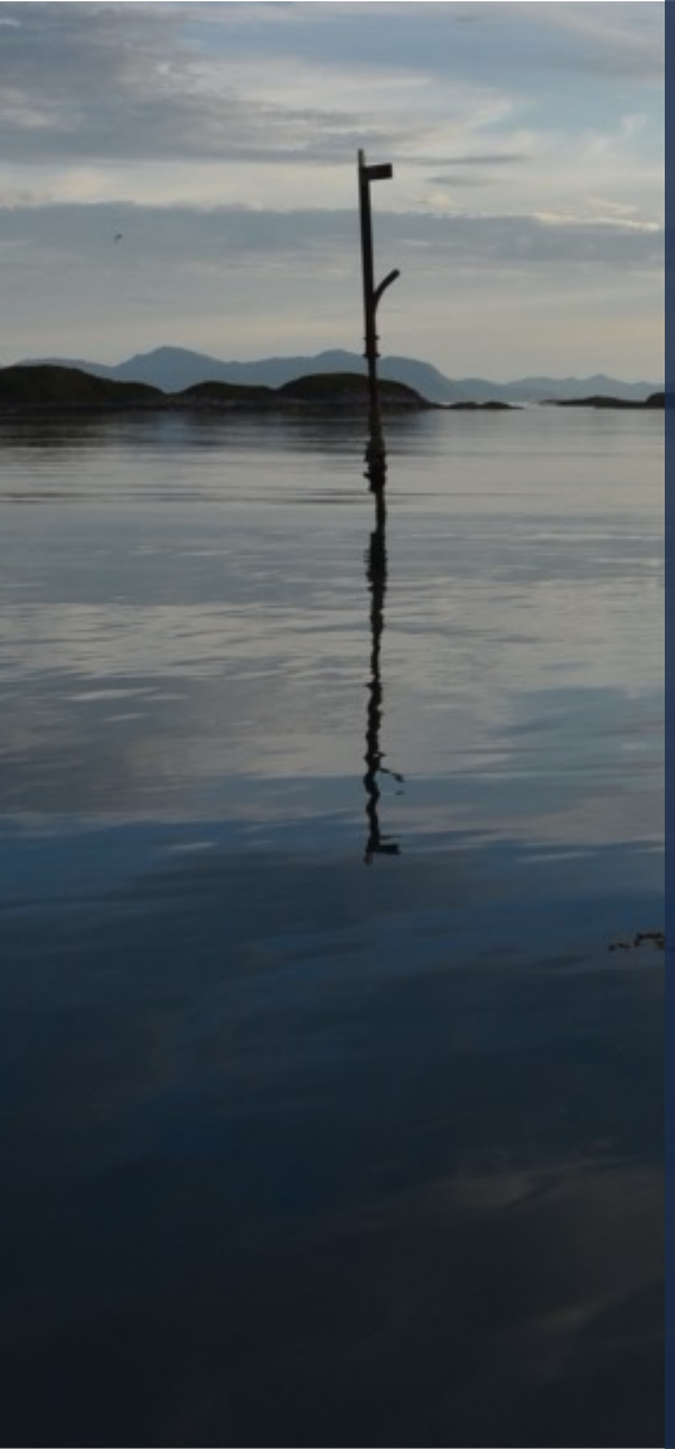
Market opportunity in mild-to-moderate disease



Properties of drug candidate HRO350

Administration	Oral (soft capsules)
Active substance	First-in-class active pharmaceutical ingredient (API)
Psoriasis indication	Mild-to-moderate disease
Severity	Few treatment options for non-severe disease

PASI: Psoriasis Area and Severity Index (0-72 point scale where >10 is moderate-to-severe and severe disease)
Source: HRO350 Commercial Opportunity Assessment in Psoriasis, IQVIA report
*Oral (e.g. fumarates, methotrexate, apremilast)
** Injectables (e-g-. adalimumab, ustekinumab, ixkizumab)



HeROPA study

HRO350 in mild-to-moderate psoriasis

Study design

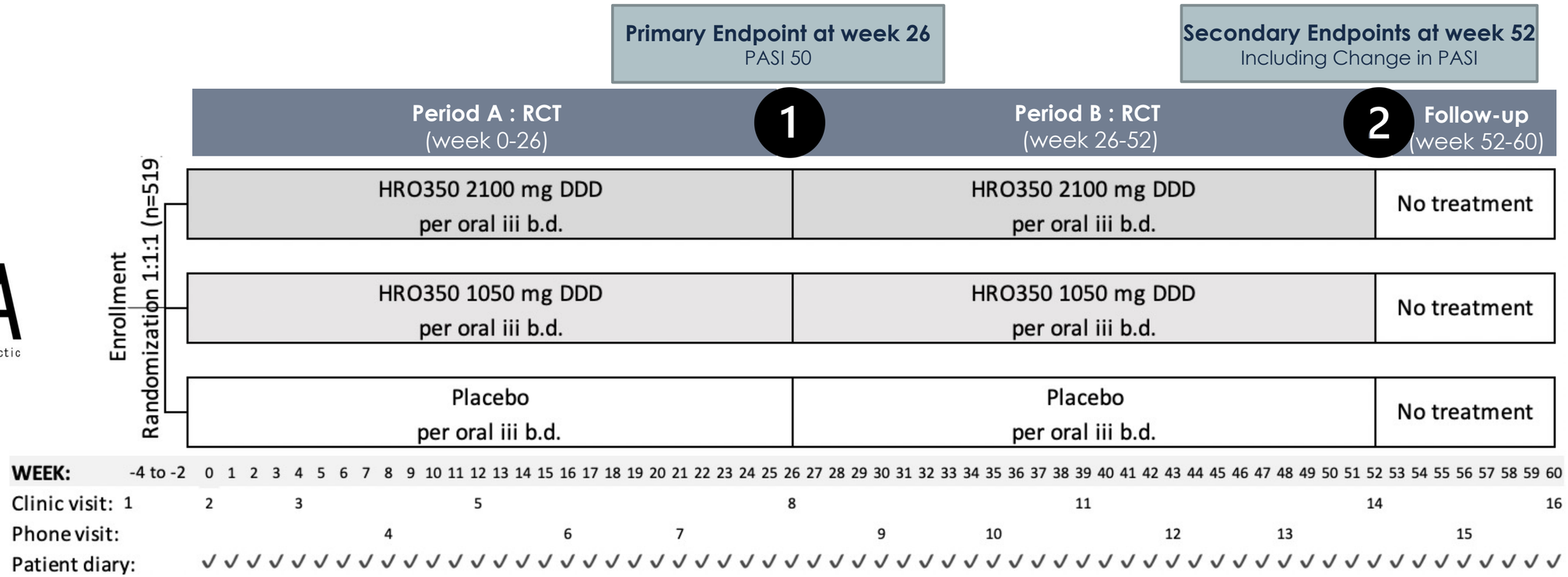
HeROPA

HeROPA Phase IIb clinical trial design

Large phase IIb study investigated efficacy, safety, and dose of HRO350 versus placebo

- Included **521 patients** started late January 2023 in the UK and March 2023 in Germany, Poland, Finland and Norway
- Protocol designed based on **Scientific Advice from the EMA**

HeROPA
Herring Roe Oil Phospholipids in Psoriasis by Arctic



PASI: Psoriasis Area and Severity Index (0–72-point scale where < 10 is mild-moderate disease); RCT: Randomized Controlled Trial. U CT number: 2022-501850-12-00
EudraCT number: 2021-003684-96
b.d. = twice daily; iii = three capsules; DDD = defined daily dose

HRO350 is a first in class asset with phospholipid esters as API

HRO350 is a **unique** lipid matrix with **biologically active phospholipids**

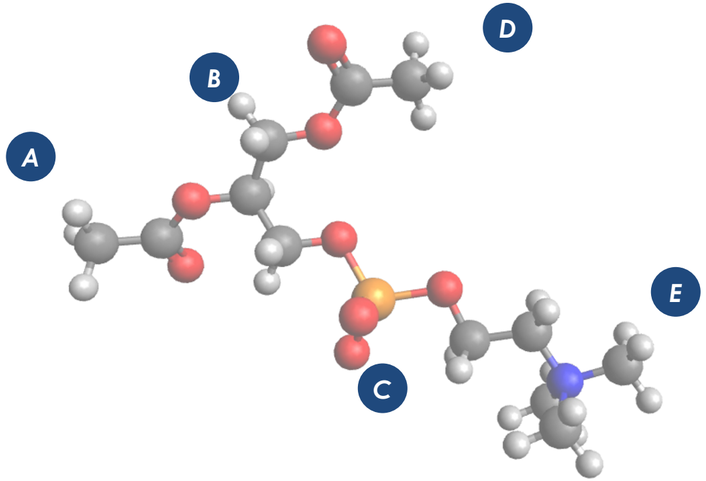
Proprietary lipid extract of phospholipid esters from **herring roe** (Clupea harengus)

Manufactured according to **GMP**

Cellular data on API and immunomodulation[1-3]

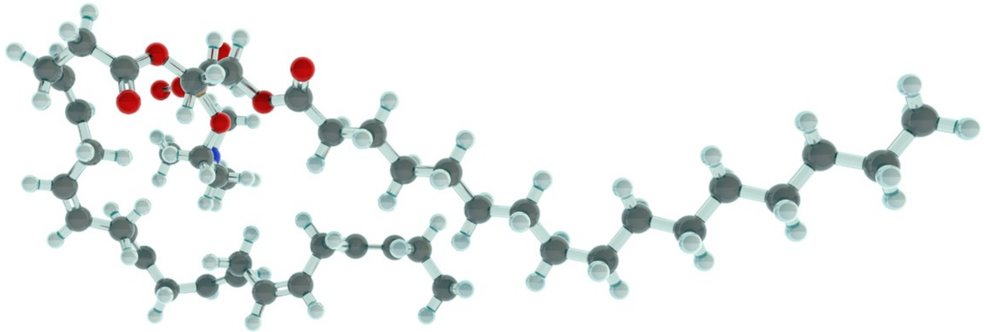
Active substance (API):
PEHeRo (Phospholipid Esters from Herring Roe)
IRIS Substance ID: 300000046327
EV Medicinal Product Code: PRD9919073

Core structure of phospholipid esters from herring roe



A FATTY ACID
B GLYCEROL
C PO_4
D FATTY ACID
E ALCOHOL

Example phospholipid: PC(22:6n3/16:0)



API: Active Product Ingredient; GMP: Good Manufacturing Practice
References: 1) Forskningsradet (Research Council of Norway), Properties of phospholipids d Herring Roe in Psoriasis, available online 2) Ringheim-Bakka, TA et al. Herring roe PLs promote SPM biosynthesis in macrophages and a keratinocyte/fibroblast co-culture as model of psoriasis, PREPRINT, bioRxiv 2025.02.20.639253; doi: https://doi.org/10.1101/2025.02.20.639253. 3) Mildenberger, J et al. Herring roe oil exerts anti-psoriatic and immunomodulatory effects on the IL-17/23 signaling axis in macrophages, T-cells and a keratinocyte and fibroblast co-culture, PREPRINT, bioRxiv 2025.04.22.650092; doi: https://doi.org/10.1101/2025.04.22.650092.

HRO350

Mode of action & resolution of inflammation

Resolve - not block - inflammation: a therapeutic frontier

HRO350 API (PEHeRo) promotes SPM biosynthesis in immune cells with implications for the treatment of psoriasis

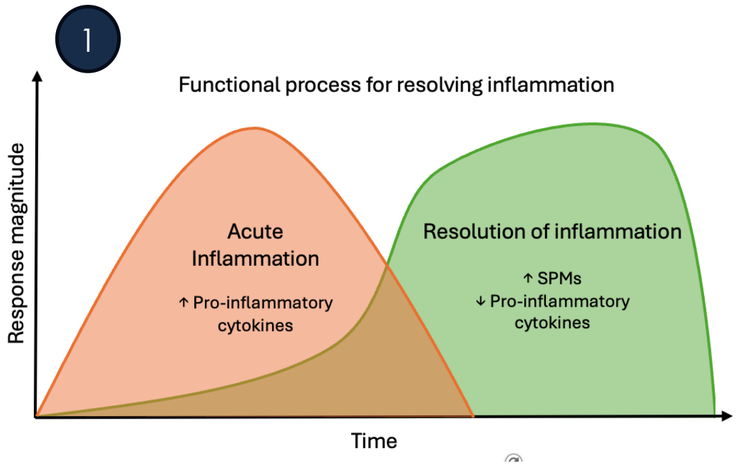
Specialized pro-resolving mediators (SPMs) are a type of bioactive lipids that actively terminate inflammation and drive the restauration of tissue homeostasis [1]

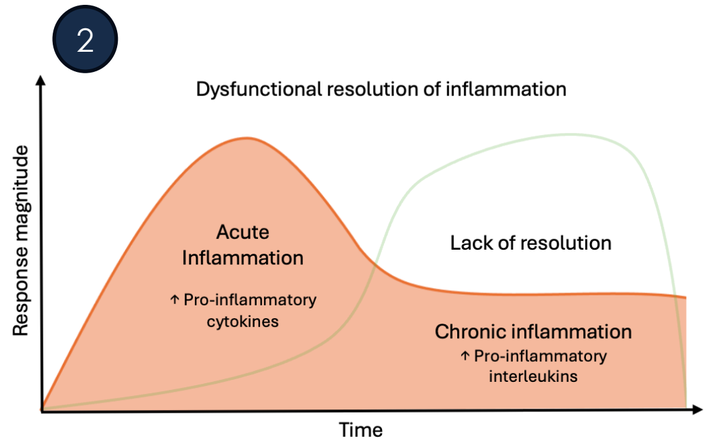
Lipid mediators are **elevated in lesional psoriatic skin**[3].

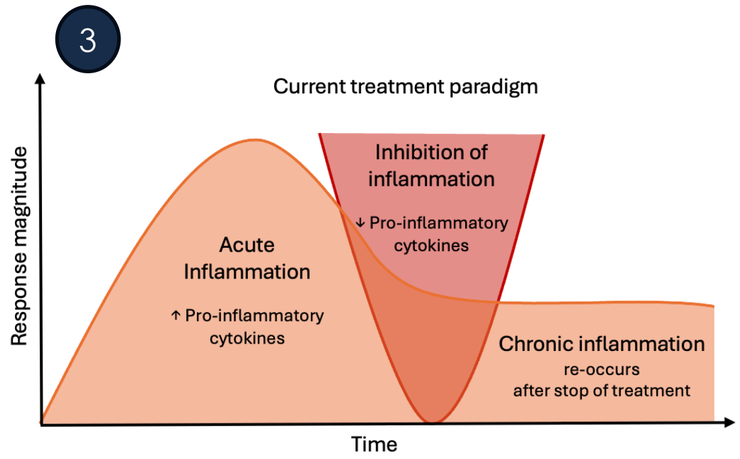
Most existing drugs are designed to reduce inflammation by inhibiting pro-inflammatory cytokines

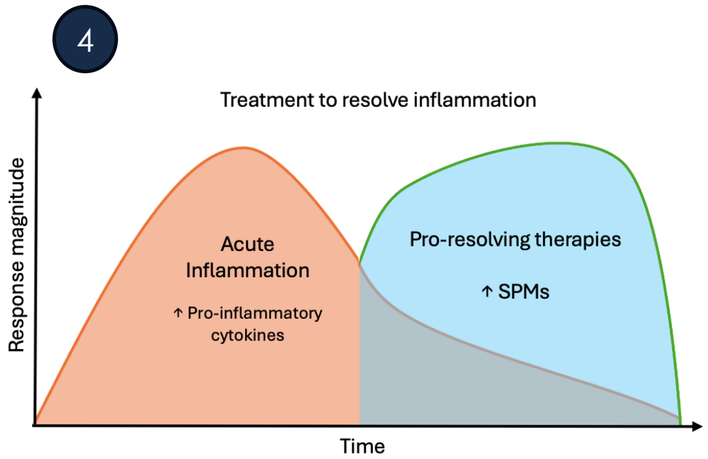
Data on SPMs supporting an **anti-inflammatory action of HRO350, and PEHeRo specifically**

- upregulating the production of SPMs which promote a shift towards a protective and possibly reparative phenotype of monocyte-derived macrophages







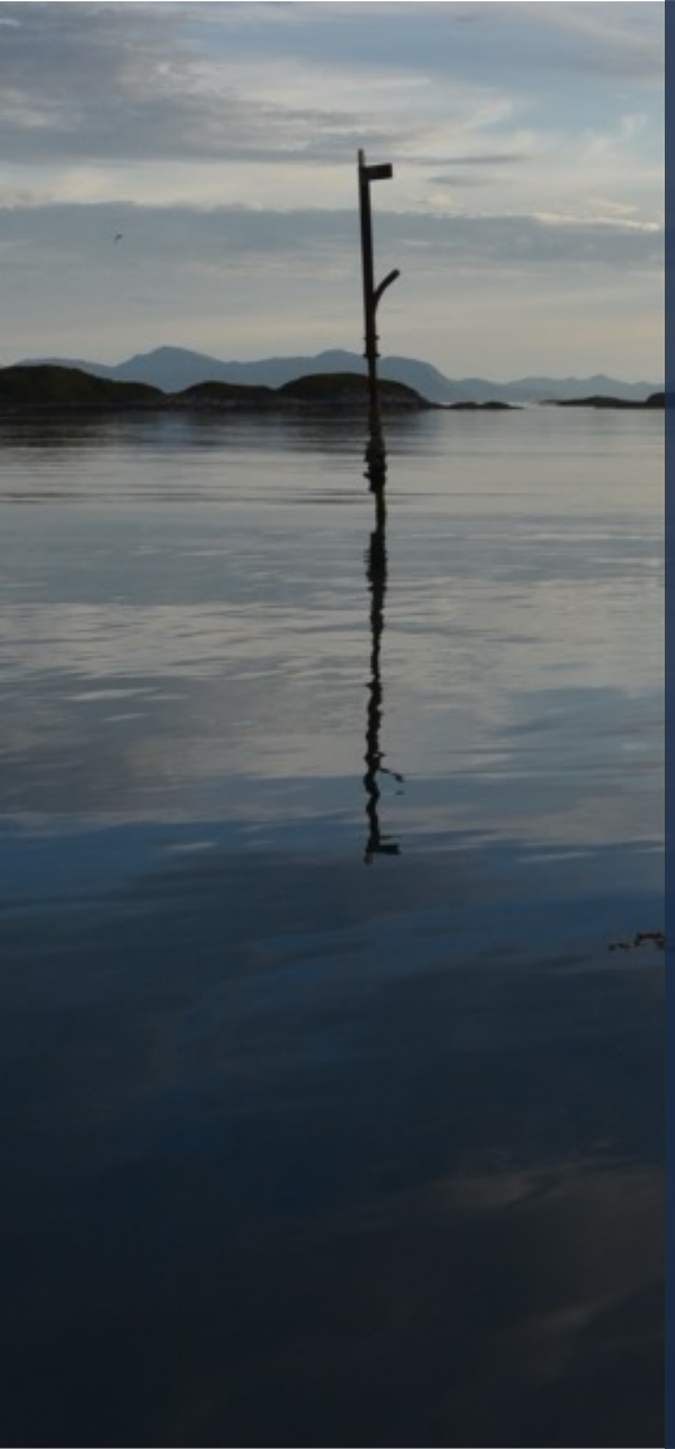


Fullerton, J., Gilroy, D. Resolution of inflammation: a new therapeutic frontier. *Nat Rev Drug Discov* **15**, 551–567 (2016). https://doi.org/10.1038/nrd.2016.39

Park J, Langmead CJ, Riddy DM. New Advances in Targeting the Resolution of Inflammation: Implications for Specialized Pro-Resolving Mediator GPCR Drug Discovery *ACS Pharmacol. Transl. Sci.* 2020, 3, 1, 88–106;

Serhan CN, Chiang N, Dalli J. The resolution code of acute inflammation: Novel pro-resolving lipid mediators in resolution. Seminars in Immunology. 2015 May;27(3):200-215. DOI: 10.1016/j.smim.2015.03.004. PMID: 25857211; PMCID: PMC4515371.

Ringheim-Bakka T, Mildenberger J, Dalli J, Saliani A, Petrucelli F, Busygina M, Mancinelli D, Gammelsæter R. Phospholipid Esters from Herring Roe promotes SPM biosynthesis in human monocyte-derived macrophages with implications for the treatment of psoriasis. Poster (37) at the 9th European Workshop on Lipid Mediators, June 26-28th, 2024.



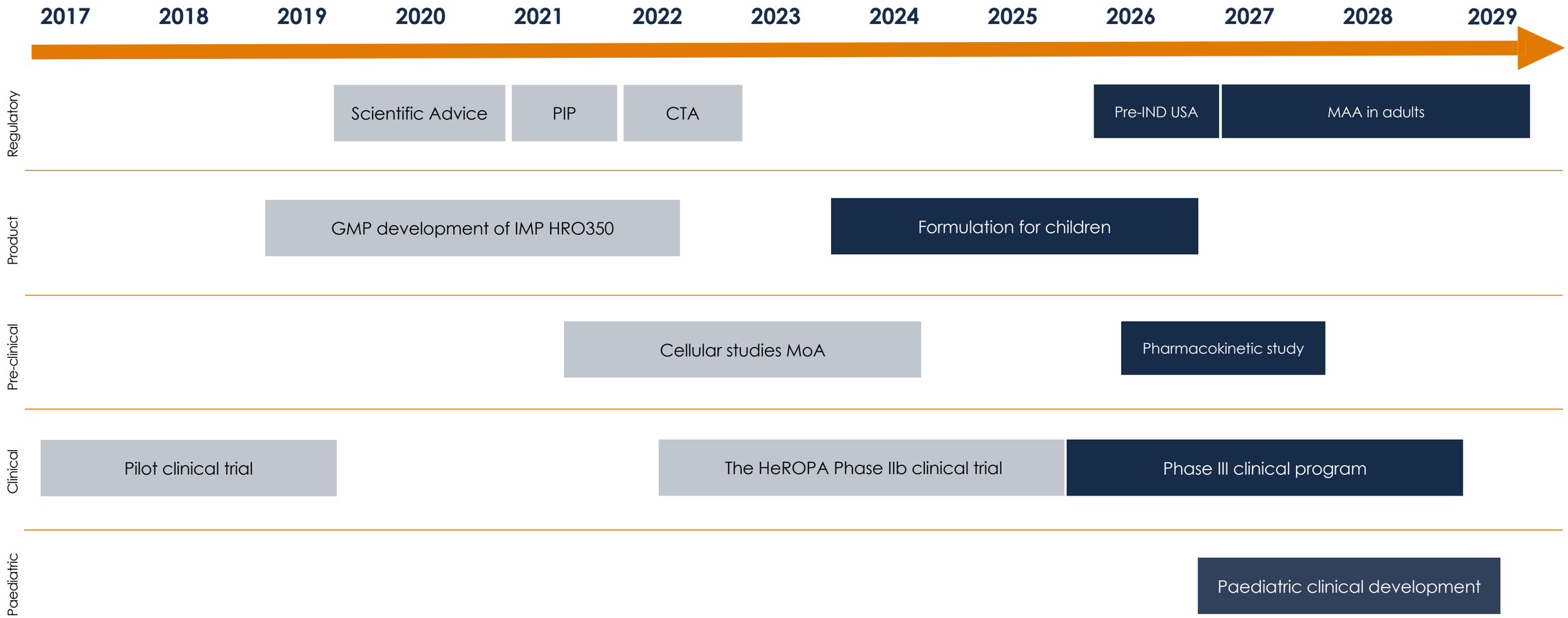
ARCTIC BIOSCIENCE

HRO350
Clinical development plan

HeROPA

HRO350 drug development program in psoriasis

Updated plan



MAA: Marketing Authorization Application; IMP: Investigational Medicinal Product. MoA: Mode of Action; IMPD: Investigational Medicinal Product Dossier; CTA: Clinical Trial Application. Scientific Advice with EMA. PIP: Paediatric Investigation Plan agreed with with the EMA Pediatric Committee*in Q1 2022.

THANK YOU

Our gratitude to the patients who participated in the HeROPA study

HeROPA investigators and clinics:

Norway:
Haukeland University Hospital
Ålesund hospital
Stavanger University Hospital
Nordlandssykehuset

United Kingdom:
Salford Royal hospital
Kiltearn Medical Centre
Newquay Health Centre
Waterloo Medical Centre
Heart of Bath Surgery
University Hospitals Dorset
Sherbourne Med Centre
University Hospital of Durham
The practice of health
Trowbridge Health Centre
St Clare Medical centre
Kingsmill Hospital
Lakeside Medical Research
Suffolk Primary Care - Haven Health
Breckland Alliance - Grove Surgery
Concord Medical Centre
Royal Primary Care Ashgate
Honiton Surgery
Hathaway Medical Centre
Rowden Surgery
West Walk Surgery
Clarence Medical Centre
Carn to Coast Health Centres

Finland:
CRST Helsinky Oy
CRST Turku Oy

Germany:
Fachklinik Bad Bentheim
Derma-Study-Center-FN GmbH
Universitätsklinikum Münster (UKM)
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Contact

Arctic Bioscience AS

Business address:

Industrivegen 42

6155 Ørsta

Norway

www.arctic-bioscience.com

CEO: Christer Valderhaug

christer@arctic-bioscience.com

Phone: +47 92084601

Medical Director: Runhild Gammelsæter

runhild@arctic-bioscience.com

Phone: +47 95933436

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