



Reformulating the Future

# New Product Candidate – HY-083

22 November 2022

# Forward-Looking Statements

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# Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING



Changing dose and/or route of administration

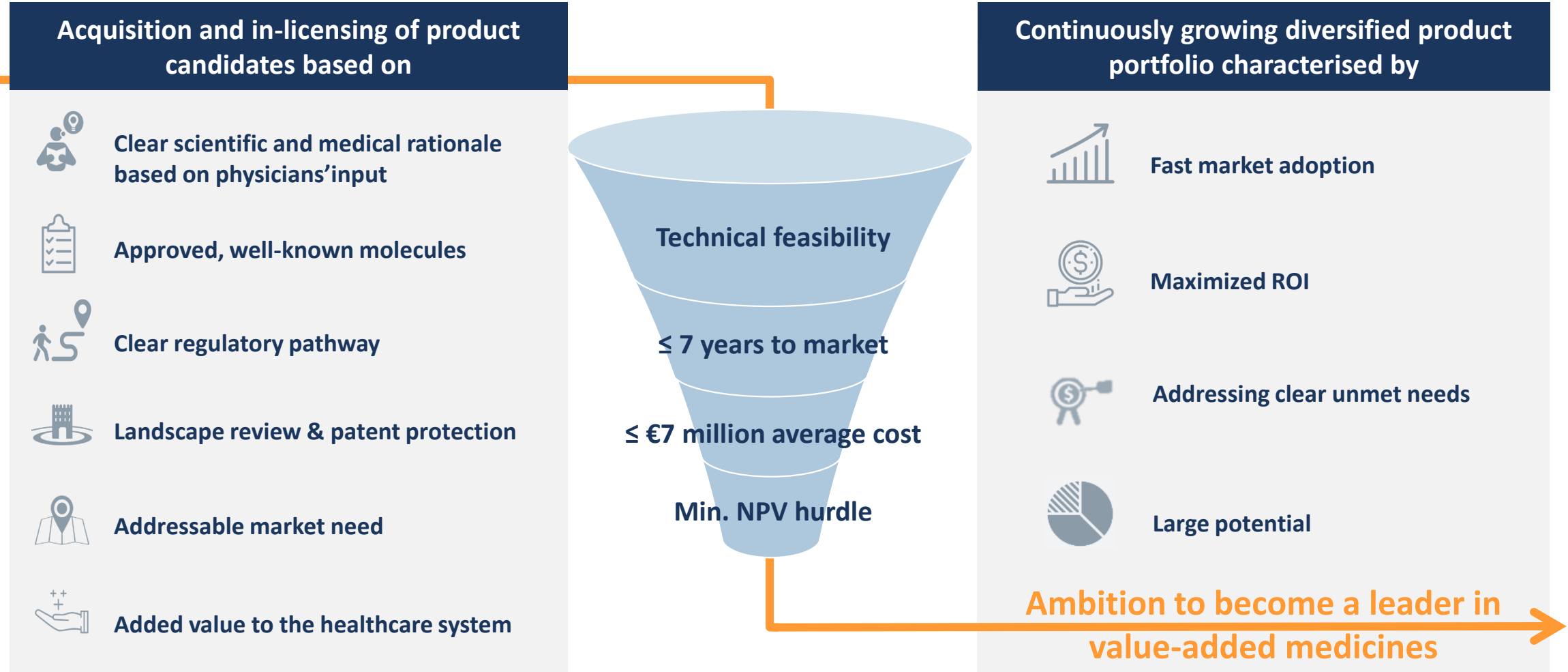
REPURPOSING/  
REPOSITIONING



New therapeutic uses

For the benefit of patients, physicians, payors

# To Drive Continuous Growth and Create Shareholders' Value



# Broad, Innovative Portfolio\*: Expand to ~30 Assets before 2025

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
<b>CARDIOVASCULAR (CV) PORTFOLIO</b>			<b>Up to 7 years</b>			
Sotalol IV	IV	Atrial fibrillation	<i>Launched in U.S./partnered with AltaThera</i>			
Aspirin IV U.S.	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				
Dofetilide IV	IV	Atrial fibrillation				
Metolazone IV	IV	Congestive heart failure				
HY-074	IV	Acute coronary syndrome				
HY-075	Oral Liquid	Coronary heart disease				
<b>OTHER VALUE-ADDED PORTFOLIO</b>			<b>Up to 7 years</b>			
Maxigesic® IV	IV	Post-operative pain	<i>Licensed in &gt;100 countries/partnered with AFT Pharmaceuticals</i>			
HY-004	Oral Liquid	Specific dental indication				
Miconazole-DB	Topical	Severe and rVVC				
Plecoid™ Agent	IV	AML/SCLC				
Alenura™	PFS	IC / PBS				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				

\* Our high barrier generic products, TXA RTU, HY-038, HY-016 and Fusidic Acid Cream have not been included in the above

Intended to be commercialised by Hyloris in the U.S.  
 Intended to be commercialised with partner

# Product Candidate HY-083

Nasal Spray in the treatment of Idiopathic Rhinitis

# Disease overview

” Chronic rhinitis is best defined by the long term presence of two or more of the three following nasal symptoms: **sneezing, runny nose, stuffy nose.**

” Idiopathic rhinitis is chronic rhinitis with **no identifiable cause**, and thus an absence of preferred treatment: trial and error.

It originates from an overexpression of TRPV1-receptors on **sensory nerves in the nose**, which sense changes in temperature, humidity or environmental triggers.

Discovery of TRPV1-receptors was awarded the **2021 Nobel Prize** in Physiology & Medicine.

- Estimated to affect around 7% of the adult population in the USA , incidence is on the rise
- If left untreated, the condition can increasingly impact quality of life
  - Interrupted sleep
  - Drowsiness in the daytime
  - Irritability
  - Poor concentration
- Patients usually wait ~8 years before seeing a specialist

# Diagnosis and treatment pathway

Trial and error approach leads to unnecessary surgery

## Infectious Rhinitis

## Allergic Rhinitis

## Non-Allergic Non-infectious Rhinitis

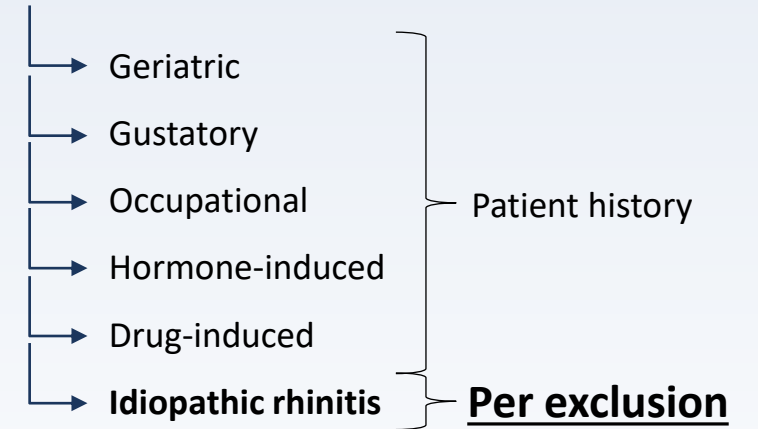
### Presentation

Discolored secretions  
Crusting

Positive skin-Prick-Test  
Specific IgE in serum

No sign of sensitization

### Patient identification



### Available treatments

Anti histamines  
Nasal cortocoids  
Decongestants (oral/intranasal)

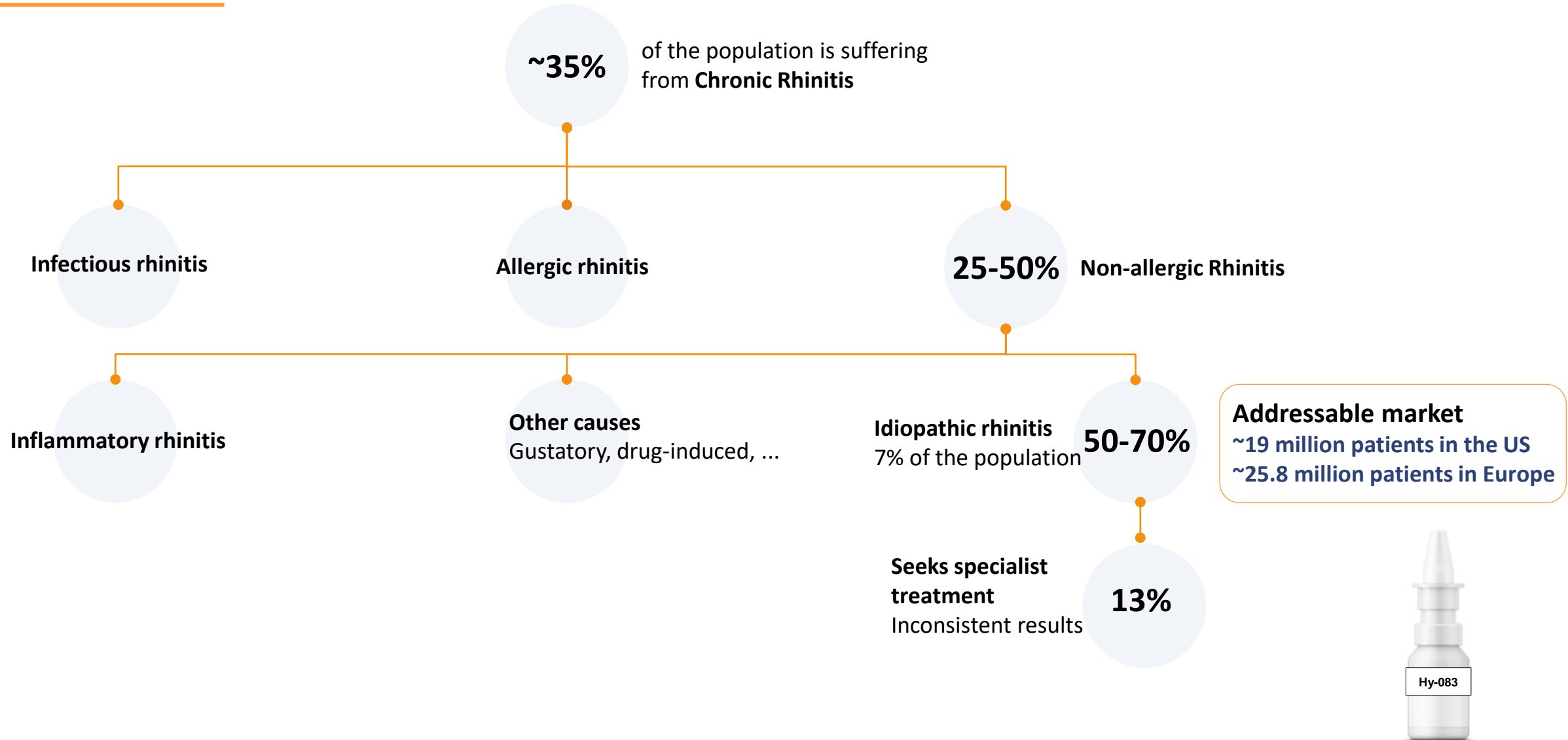
**FIRST LINE CARE**  
General practitioner  
Pharmacy

**SPECIALIST CARE**  
Rhinologist

**Mild to moderate**  
Conservative treatments  
Saline nasules  
**Severe**  
Turbinate reduction surgery



# Patient population and addressable market



# Rationale for HY-083 and unmet need



Patients are typically subjected to multiple rounds of treatment failures that lead to frustration towards seeking medical care and medication use.

## Significant increase of risk of other comorbid conditions

Obstructive sleep apnea, fatigue, headache, malaise, poor appetite, weakness

## Impaired work performance in adults

Can also manifest as learning disabilities, behavioral, and psychological effects in children

## Poor Quality of Life

## Children at risk for permanent facial changes from untreated rhinitis

Increased facial length, retrognathic maxilla and mandible, and dental malocclusions from obstructed breathing

## Additional expenditures and lost time from work

Doctor appointments, medication prescriptions

**HY-083** aims to provide significant improvement and increase patient quality of life:

- ✓ New treatment where currently there is none
- ✓ Significantly minimize symptoms of Idiopathic Rhinitis
- ✓ Can avoid surgical treatment for many patients
- ✓ Reduces total overall treatment cost for this group of patients
- ✓ Low investment / Volume product
- ✓ In line with selection criteria (unmet medical need, 7 years & €7 million)

# Potential Game Changer, Geared for Growth

## MULTIPLE SHOTS ON GOAL

≤ **7 years** to market

≤ **€7 million** average cost to market

**Lower risk** as we start from existing drugs

**15<sup>1</sup> Innovative, patented, value-added** drug candidates in the pipeline

## COMMERCIAL PORTFOLIO

**2 patented products** with partners

**Addressing unmet needs**

Build **U.S. commercial** team

**Relevant improvements** for patients, physicians and the healthcare system

**Ambition to become the reference in value-added medicines over the coming years with 30 assets before 2025**

<sup>1</sup> 13+2 commercialised products, excluding our high barrier generic products, TXA RTU, HY-038, HY-016 and Fusidic Acid Cream.

# Anticipated Value Inflection Milestones in the next 12 months

## Clinical

- Starting pivotal PK clinical trial for Dofetilide IV and HY-029
- Starting Phase 2 clinical trial for Alenura™
- Completing Phase 2 clinical trial recruitment for Miconazole-DB end of 2022. Top line results in H1 2023.
- Other PK study in preparation
- Starting Phase 3 clinical trial on HY-004 (Tranexamic Acid Oral Mouth Rinse)

## Regulatory

- Atomoxetine: implementing changes to taste masking technology – FDA scientific feedback
- Additional E&L study ongoing for Maxigesic® IV – FDA submission upon completion of E&L study

## Commercial

- Commercial partnership(s)
- Continued roll-out of Maxigesic® IV and Sotalol IV with our partners

## Finance

Cash position H1 2022: €57,7m



Q&A

