

# Budesolv

Low-dose anti-allergic corticosteroid  
nasal spray with immediate relief

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# Marinomed at a glance





# Marinomed at a glance

Publicly listed biopharmaceutical company in Austria

**2006**

Foundation

**2008**

Launch of Carragelose

**2016**

Invention of  
Marinosolv

**2019**

IPO and Marinosolv  
clinical validation

**2021**

Marinosolv deal and  
Solv4U launch

**2022**

Deal with  
Procter & Gamble



Prime Market Segment of the Vienna Stock Exchange

## Therapeutic areas

### VIROLOGY

Revenue-generating  
OTC portfolio

### IMMUNOLOGY

High-value  
products in late-  
stage development

Solv4U

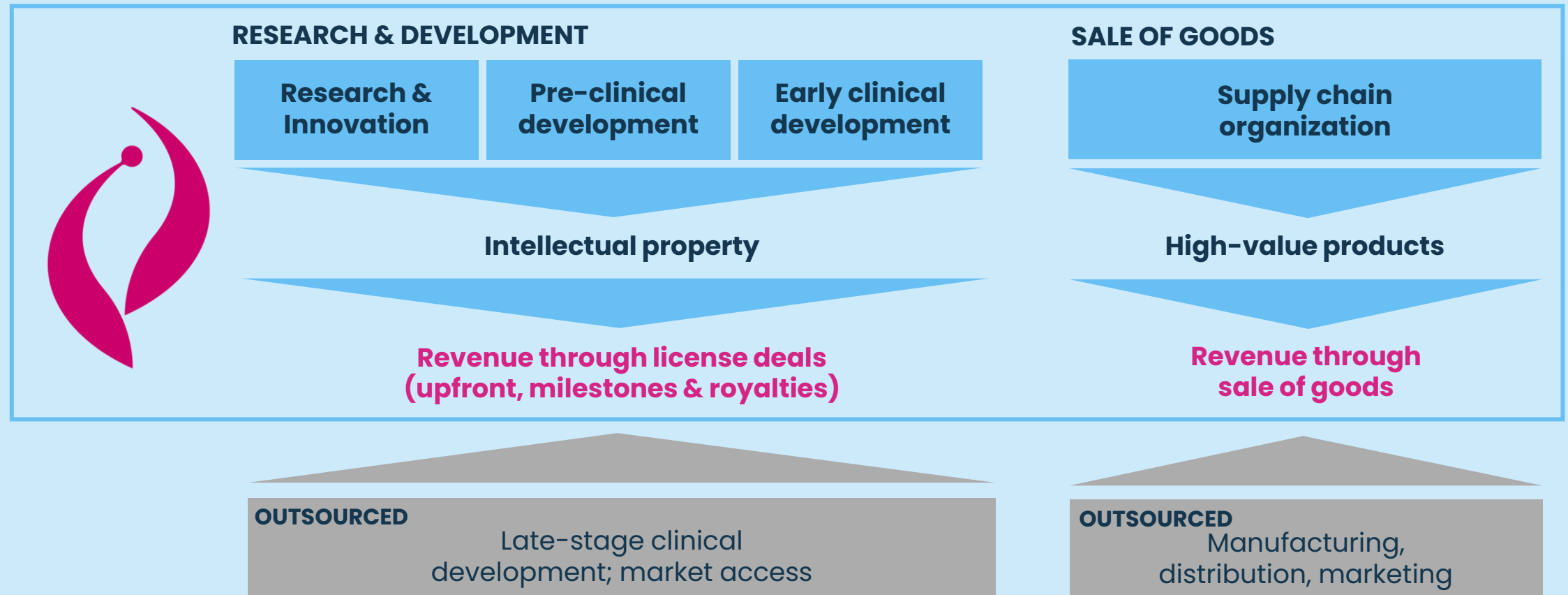
Solubilization technology  
partnerships for customers



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# Business Model

IP generation with lean organization & grow existing business



# Platforms & Therapeutic Areas

## Carragelose®

Universal **blocking of viruses and allergens** as well as moistening of mucosal tissues

### Cough & cold portfolio

Viral respiratory infections



### Allergy nasal spray

Mild allergic rhinitis



### Eye drops

Dry, irritated eyes



**VIROLOGY**

## Marinosolv®

**Solubilization** of poorly water-soluble compounds and improving **local onset of action**

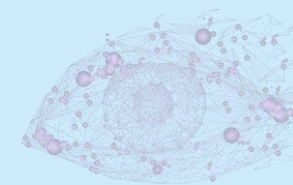
### Budesolv

Allergic rhinitis



### Tacrosolv

Inflammatory eye diseases



### Solv4U Technology partnerships

**Solv4U**

**IMMUNOLOGY**

**SOLV4U**



# Budesolv

The only low-dose intranasal, preservative free corticosteroid with strong symptom relief after first dose

**Erich Durchschlag**

S. Business Development Mgr.

+43 676 3253005

[erich.durchschlag@marinomed.com](mailto:erich.durchschlag@marinomed.com)

**Marinomed Biotech AG**

Hovengasse 25  
2100 Korneuburg, Austria



# Executive summary: Budesolv

Innovative opportunity with strong USP to challenge the total allergic rhinitis market

## Budesolv

- **Fast and strong efficacy after first dose**
- **Strongly reduced dose (~16% of originator)**
- **Preservative-free formulation**
- **Marinosolv technology-based innovation**
- **Sustainable and reduced wastewater pollution**

## Market opportunity

- Fast growing (~4,5% CAGR) allergy market of currently US\$11,4bn<sup>1</sup>
- Strong USP over marketed competitors

## Regulatory path

- Hybrid application in EU
- 505(b)(2) in the US

## Business model

- Classical license deal with downpayment, milestones and royalties
- Patent protected until 2043

## Clinical phase III

- Superior symptom relief after first dose over comparator
- Non-inferiority vs comparator after 8 days of treatment

## Safety

- Safety demonstrated in local tolerability studies
- Safety shown in clinical phase III



## Line extension

- Chronic rhinosinusitis
- Allergic asthma
- Preservative-free combination products with anti-histamines



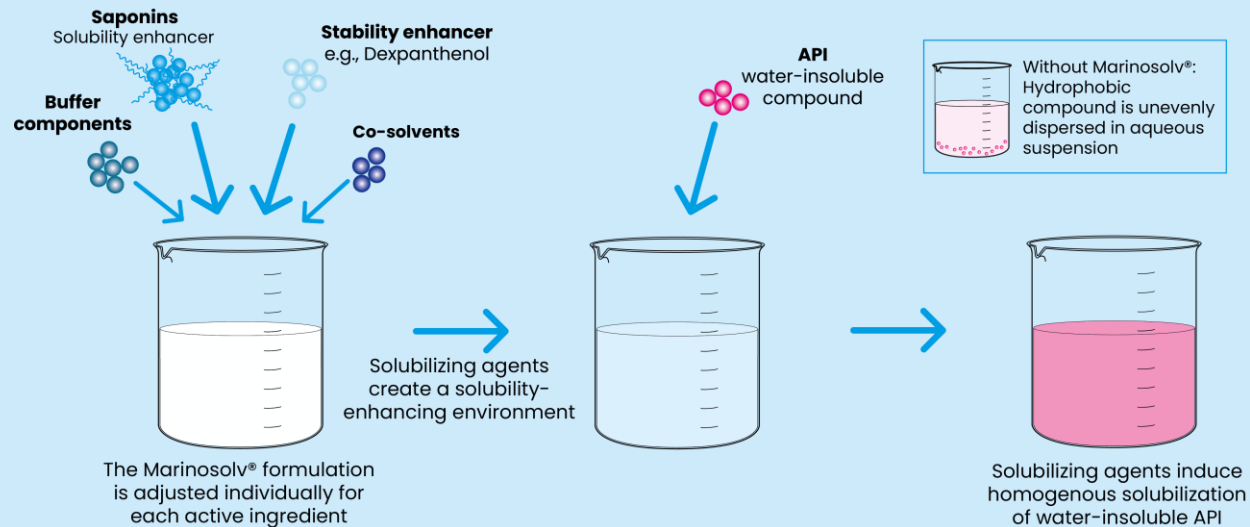


# Marinosolv® platform technology

## Formulation technology

## Capabilities / improvements

### Marinosolv® formulation & solubilization of water-insoluble API



- Solubilization of **poorly water-soluble** compounds
- Significantly increases **bioavailability**
- Allows **dose reduction & faster onset of action**
- **Reduces** pharmaceutical compounds in **wastewater**
- **Clinically validated & patent protected**
- Suitable for **sensitive tissues** such as eyes and nose

Marinosolv: High potential platform technology providing unique capabilities



# Budesolv nasal spray

The only nasal spray providing solubilized corticosteroid



Competitors



Budesolv

## Benefits of the solution

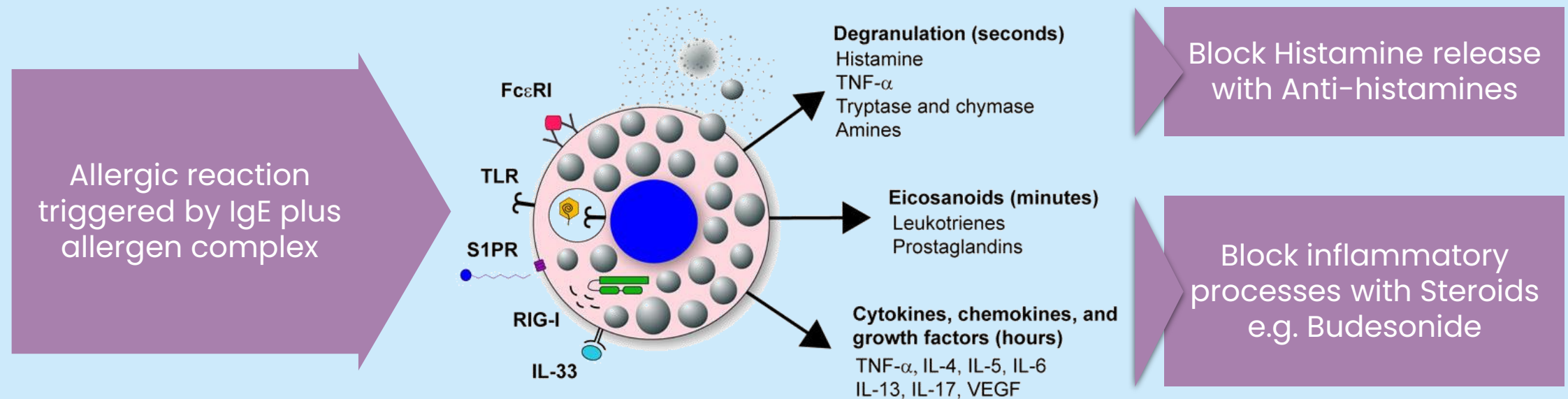
- Highly increased bioavailability
- Fast onset of action after first dose
- Low dose application (~16% of originator)
- Preservative - free formulation
- Easy to use - no shaking, high-precision dosing
- Manufacturing - Aseptic large scale production

Marinosolv allows a complete dissolution of Budesonide with significant benefits over suspension



# Pathophysiology of Allergic Rhinitis (AR)

IgE/allergen (FcεRI) complex binding to mast cells causes release of histamines and pro-inflammatory cytokines

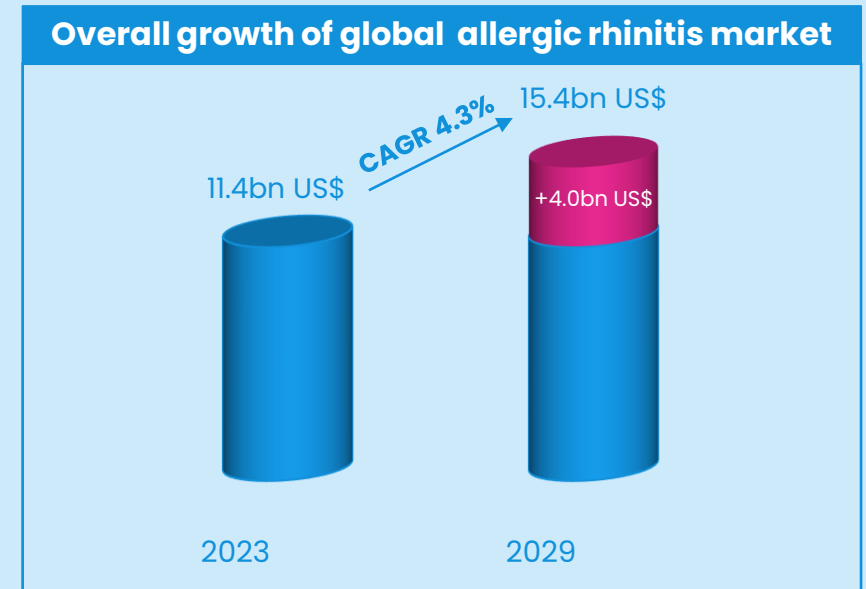
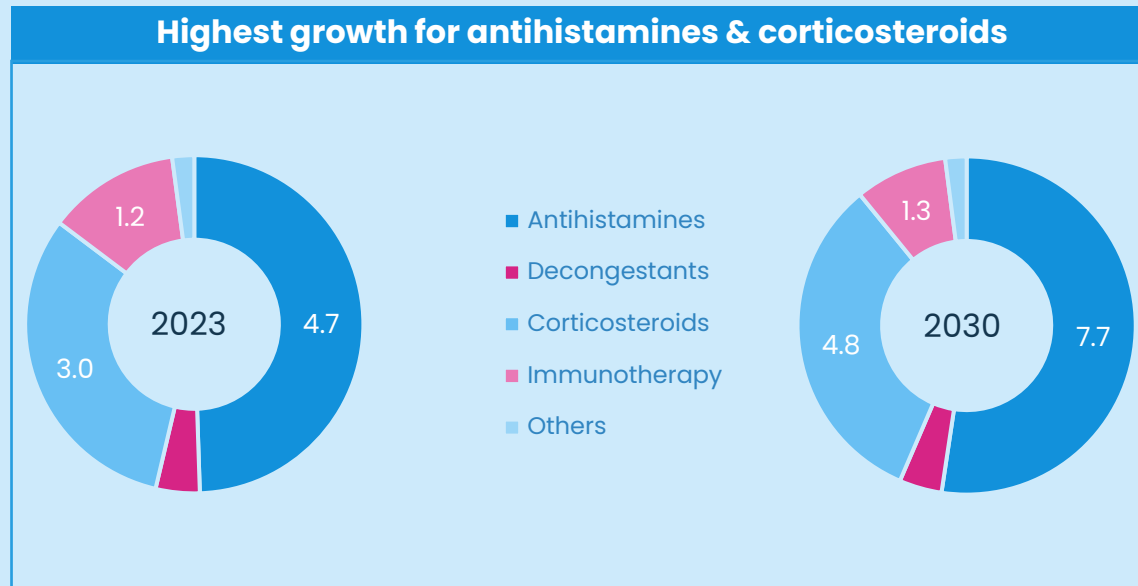


Antihistamines and corticosteroids are SoC to treat allergic rhinitis



# Allergic Rhinitis market

Huge market potential for innovative drugs in a growing market



Allergic rhinitis market expected to grow from 11.44 to 15.35 bn US\$ by 2030 (CAGR 4.3%) mainly through antihistamines and corticosteroids

# Medical need in Allergic Rhinitis (AR)

Range of therapies available, but high unmet medical need remains

	Antihistamines	Corticosteroids	Immunotherapy
Effectiveness	+	+++	++
Onset of action	+++	+	-
Patient Convenience	+++	+++	-
Side effects	-	-	--
Price	\$	\$	\$\$\$\$

Available treatments are safe & convenient but lack fast symptom relief paired with high efficacy

## The unmet medical need in allergic rhinitis

Marketed steroid drugs have slow onset of action

Antihistamines are less efficacious

Combination of therapies causes cumulative side effects

Immunotherapy is complicated and expensive

Allergic rhinitis is still underdiagnosed & undertreated

There is a growing need for steroids delivering fast efficacious & sustainable treatment

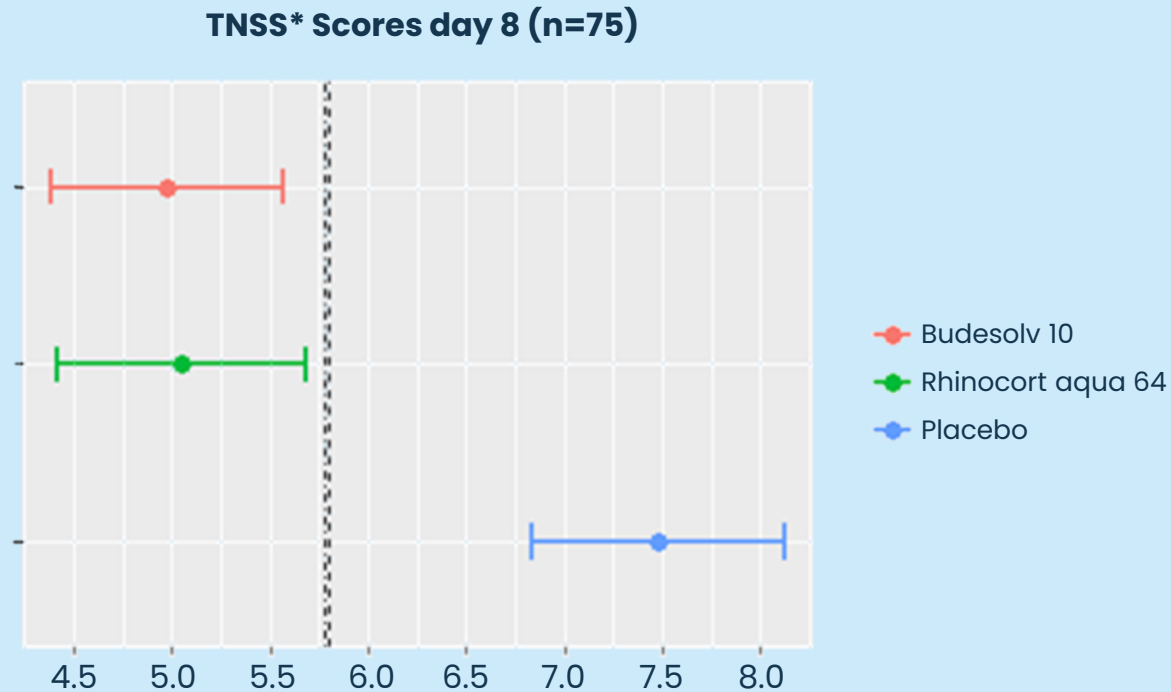
Compared to all other intranasal steroids on the market, only Budesolv shows immediate onset of action with strong symptom relief





# Primary endpoint: Non-inferiority

Budesolv clinically **equivalent** to the originator on **day 8** in phase 3 study



Treatment	Mean	SD	Median	N
Budesolv 10	4.98	2.57	4.47	75
Rhinocort Aqua 64	5.05	2.75	4.82	75
Placebo	7.48	2.80	7.47	75

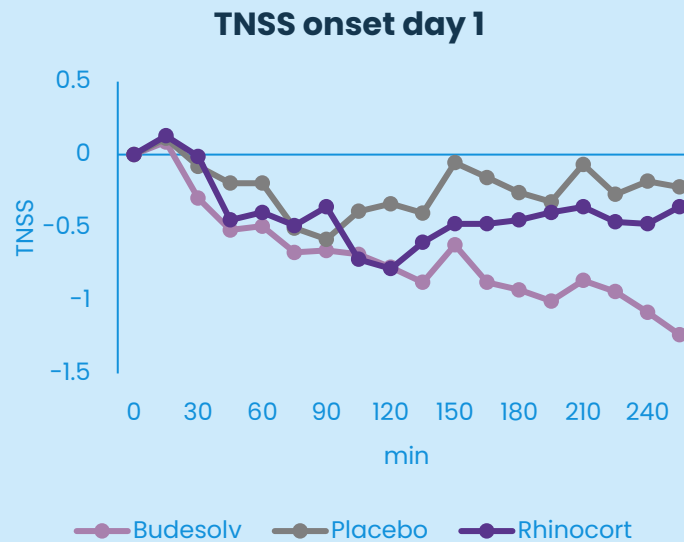
\*TNSS = total nasal symptom score (runny nose, itchy nose, congestion, sneezing)

Reduction of TNSS\* for Budesolv non-inferior vs. originator and superior over placebo

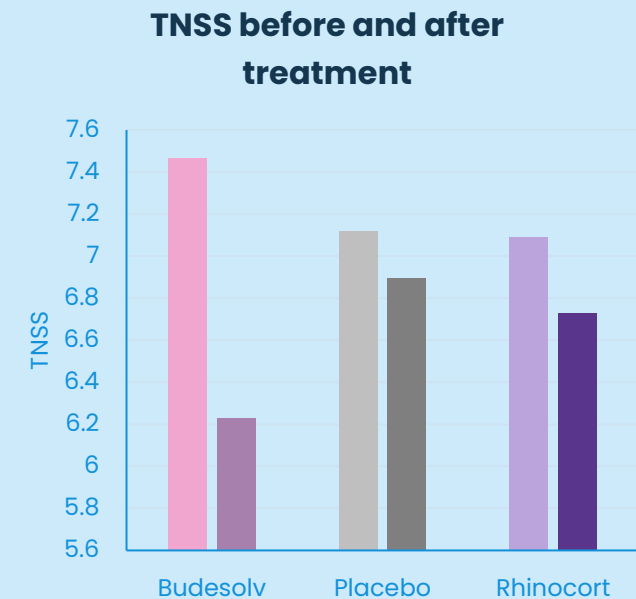


# Key secondary endpoint: Fast onset of action TNSS\*

Budesolv **superior** over originator on **day 1** in phase 3 study



Significant reduction of allergic symptoms after the first dose of Budesolv compared to marketed product



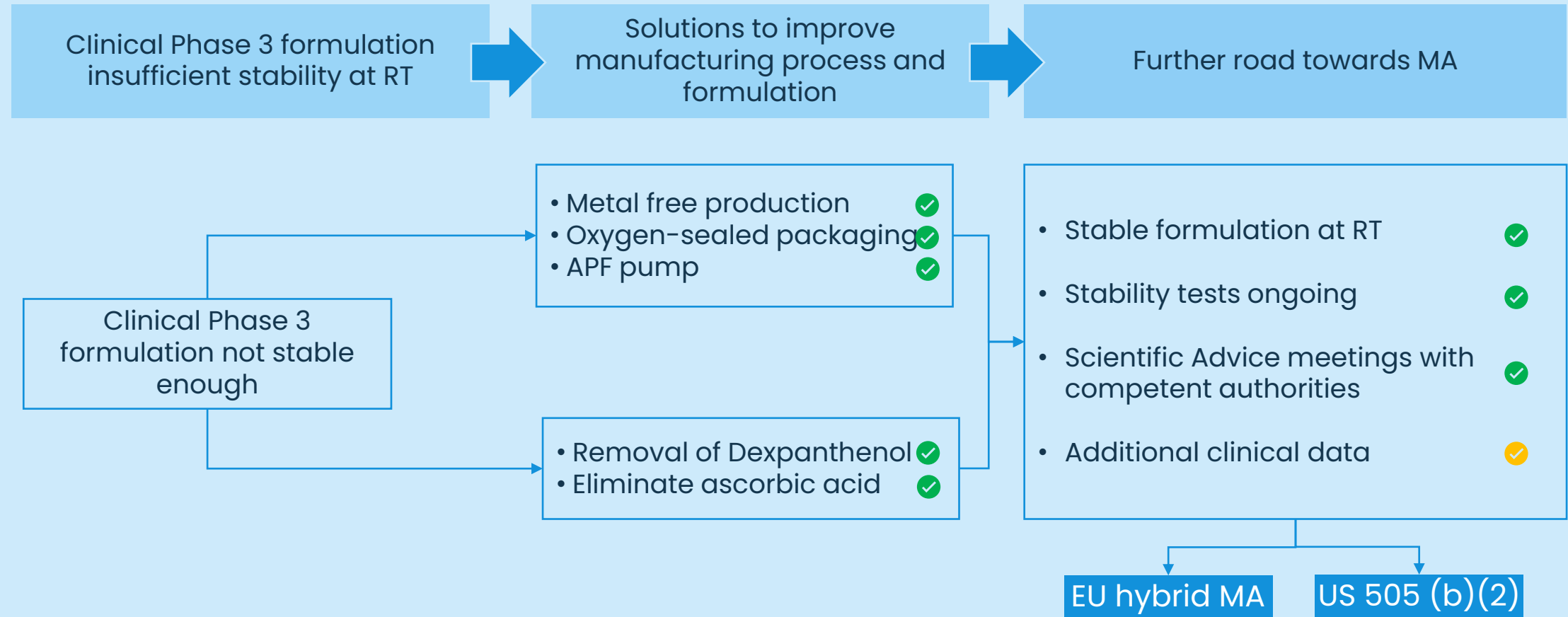
Significant reduction of TNSS after the first dose of Budesolv compared to marketed product

Budesolv is the first intranasal corticosteroid with immediate symptom relief after the first dose

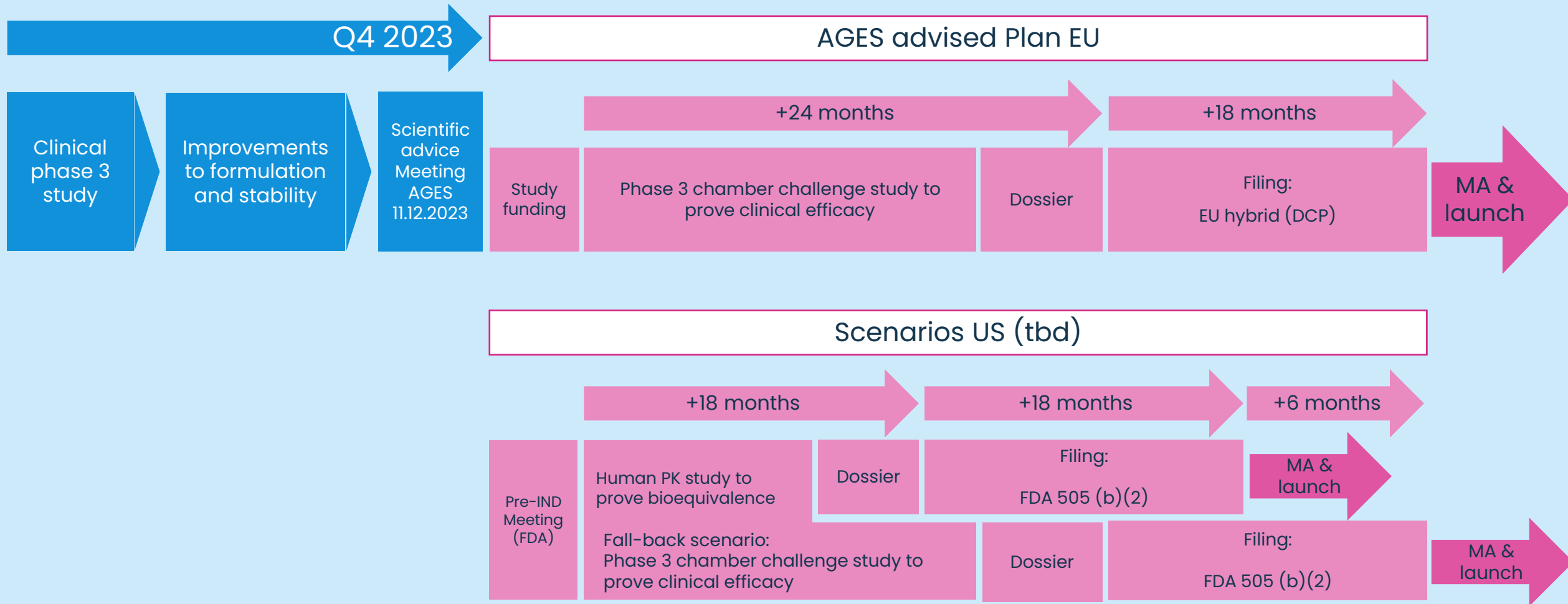
# Budesolv positioning with strong USP<sub>(s)</sub> & high market potential

	<b>Budesolv:</b>  <b>Clear Solution</b> 	<b>Competitor:</b>  <b>Suspension</b> 	<b>Budesolv Positioning</b>
Bioavailability (tissue permeation)	high 	low 	High bioavailability at low dose
Onset of action	hours 	5-8 days 	First in class fast acting nasal spray
Applied daily dose	Max. 40 µg (~ 16% of originator) 	Max 256 µg 	Less side effects ( <i>pediatrics!</i> ) less wastewater contamination
Preservatives	none 	always 	Improved local tolerability higher patient acceptance
Exclusivity	LOE not before <u>2043</u> !	Already generic	Huge market potential in total AR
Pipeline opportunities	Asthma COPD Chronic sinusitis  	none 	Potential pipeline for new indications

# Path to launch formulation and marketing authorization



# Timeline to obtain MA in EU & US





# Budesolv

First low-dose intranasal corticosteroid  
with immediate relief after initial dose

**Erich Durchschlag**

S. Business Development Mgr.

+43 676 3253005

[erich.durchschlag@marinomed.com](mailto:erich.durchschlag@marinomed.com)

**Marinomed Biotech AG**

Hovengasse 25  
2100 Korneuburg, Austria



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