

# BIOPHARM

SECURE A  
LEADING  
POSITION

BY LEVERAGING  
FULL PORTFOLIO  
AND EXPANDING  
INTO ADJACENT AREAS



# Forward-looking statements

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including this presentation as well as the company's statutory Annual Report 2018 and Form 20-F, which were both filed with the SEC in February 2019 in continuation of the publication of the Annual Report 2018, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to:

- Statements of targets, plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto,
- Statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures,
- Statements regarding future economic performance, future actions and outcome of contingencies such as legal proceedings, and
- Statements regarding the assumptions underlying or relating to such statements.

These statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific. Novo Nordisk cautions that a number of important factors, including those described in this presentation, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results include, but are not limited to, global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations, delay or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and production, product recalls, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, reliance on information technology, Novo Nordisk's ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees, and failure to maintain a culture of compliance.

For an overview of some, but not all, of the risks that could adversely affect Novo Nordisk's results or the accuracy of forward-looking statements in this presentation, reference is made to the overview of risk factors in 'Risk management enables better decision-making' on pp 41-43 in the Annual Report 2018.

Unless required by law, Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this presentation, whether as a result of new information, future events or otherwise.

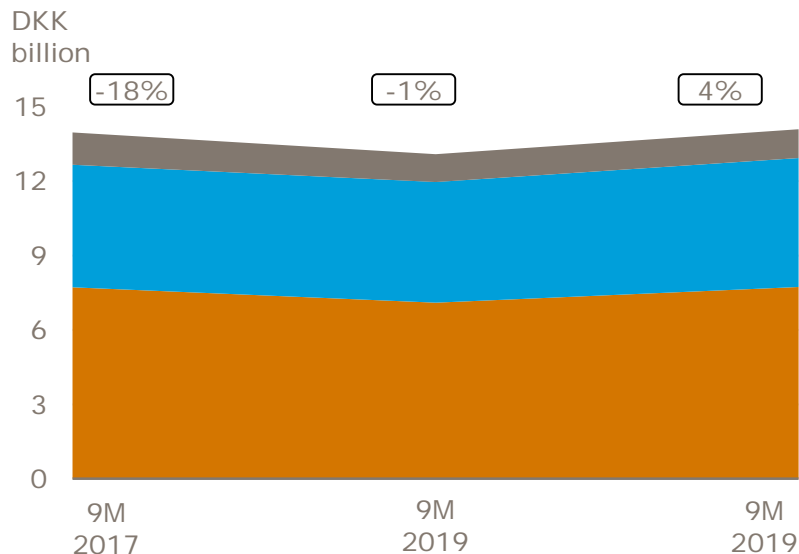
## Important drug information

- Victoza® is approved for the management of type 2 diabetes only
- Saxenda® is approved in the USA and the EU for the treatment of obesity only

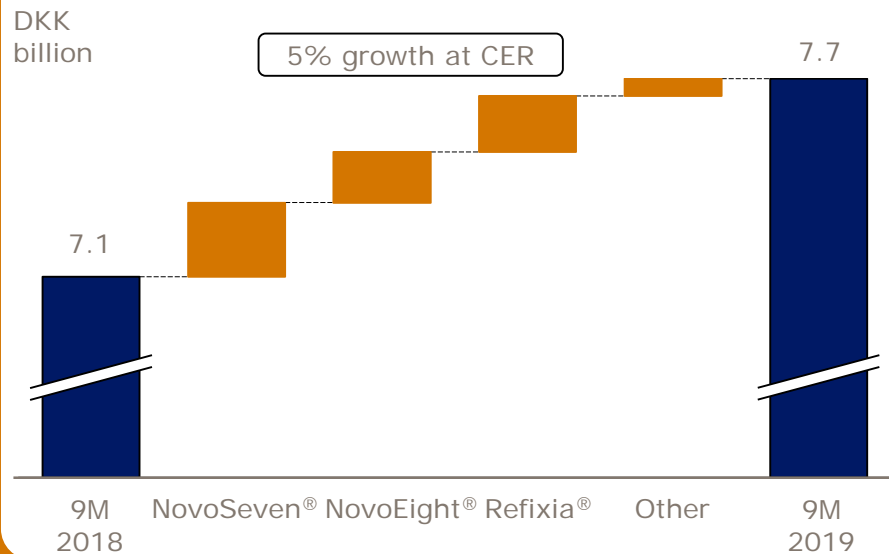
**Note: All notes, sources and abbreviations for this presentation are found in the appendix.**

# Solid commercial execution is driving 4% sales growth in first nine months of 2019

Biopharm has returned to growth with 4% sales growth in first nine months of 2019

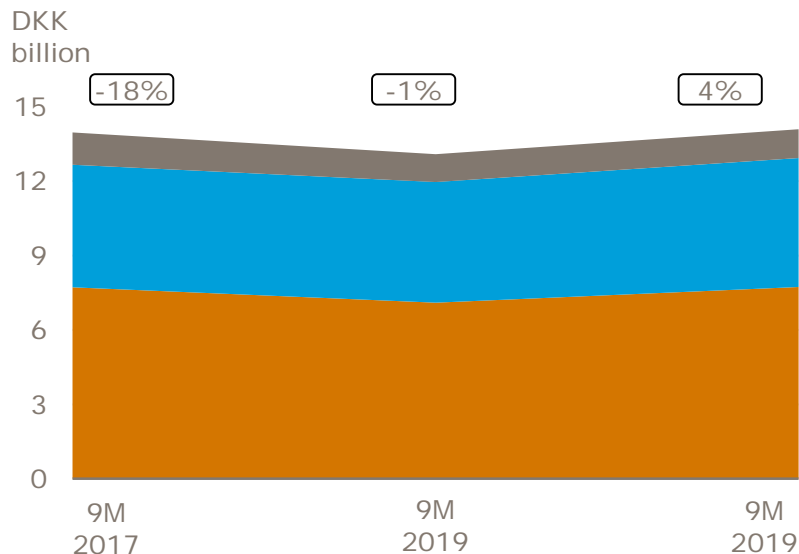


Added sales in the haemophilia product portfolio



# Solid commercial execution is driving 4% sales growth in first nine months of 2019

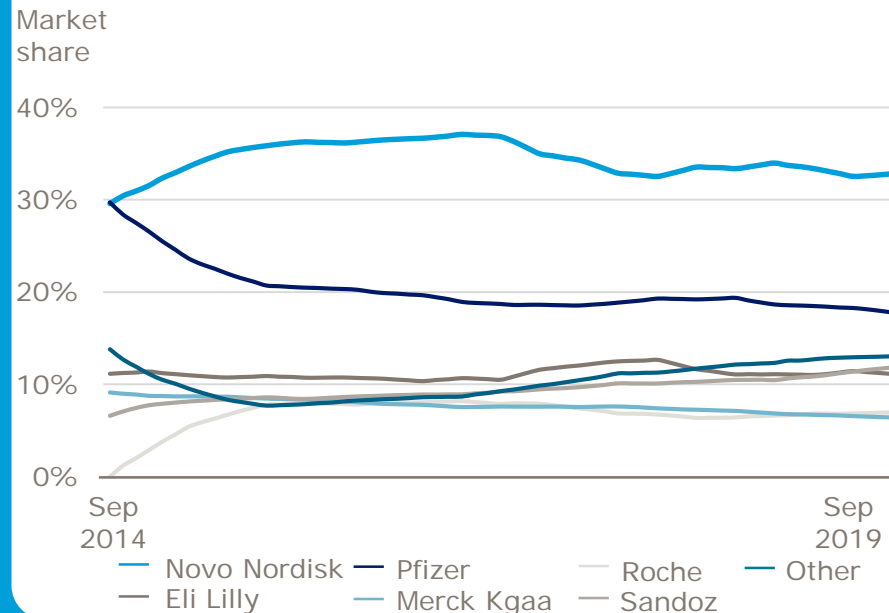
**Biopharm has returned to growth with 4% sales growth in first nine months of 2019**



CAPITAL  
MARKETS  
DAY

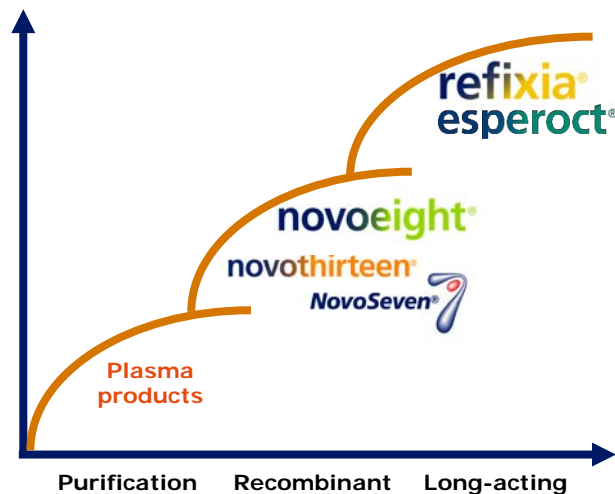
Haemophilia Growth disorders  
Other Growth at CER

**Norditropin® value leadership maintained despite increasing competition**

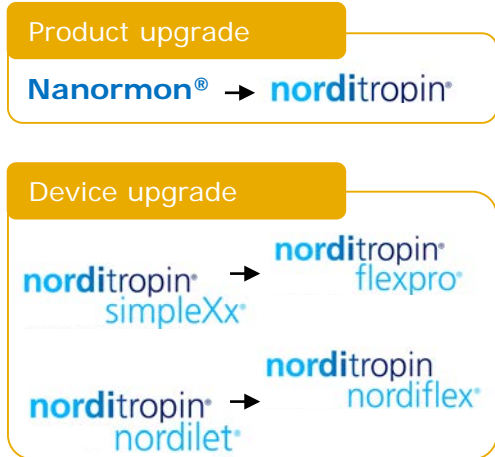


# Current and future growth is supported by a genuine portfolio of products and devices with an intensive launch agenda

## Well-positioned with a full haemophilia product portfolio



## Evolution through product and device upgrades for GHD



## Uninterrupted global launches and new indications

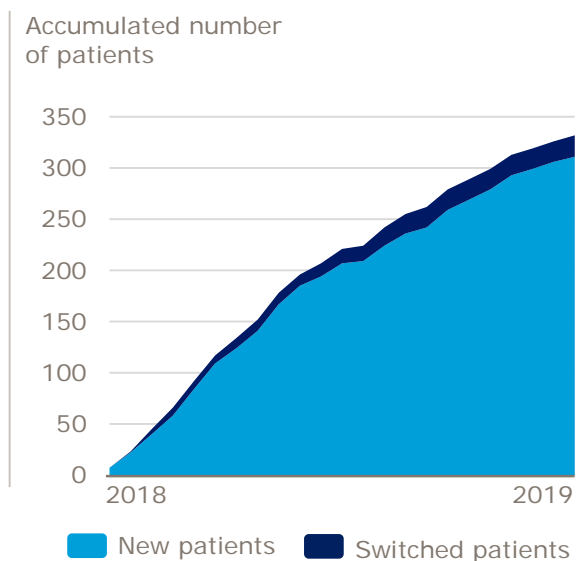
	Current launches		Towards 2022
refixia®	15	+	15
esperoct®	2	+	25
norditropin® <i>Noonan syndrome, EU device upgrades</i>	16	+	30

# Biopharm exhibits the traditional features of a strong speciality care unit

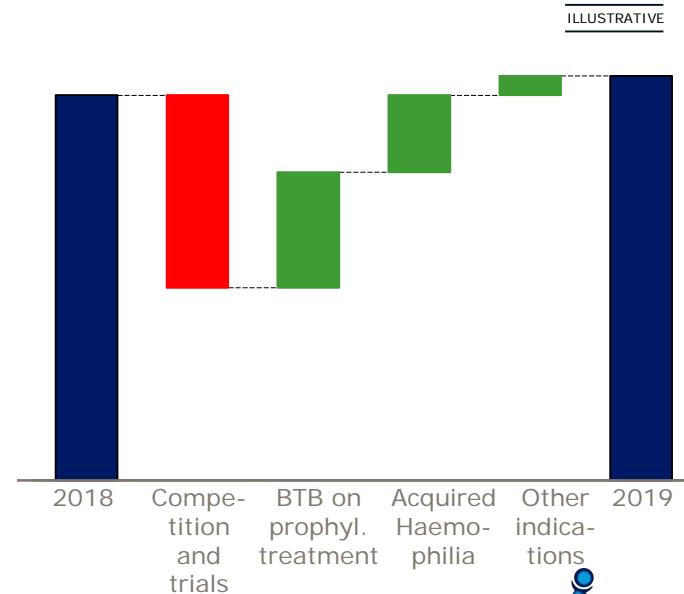
## Biopharm ticks all speciality care boxes

- ✓ **Focused health care professional base**
- ✓ **Skilled scientific medical sales force and commercial unit**
- ✓ **Deep scientific knowledge**
- ✓ **Robust life-cycle management**

## Identify new patients in rare diseases, such as Noonan syndrome in Japan

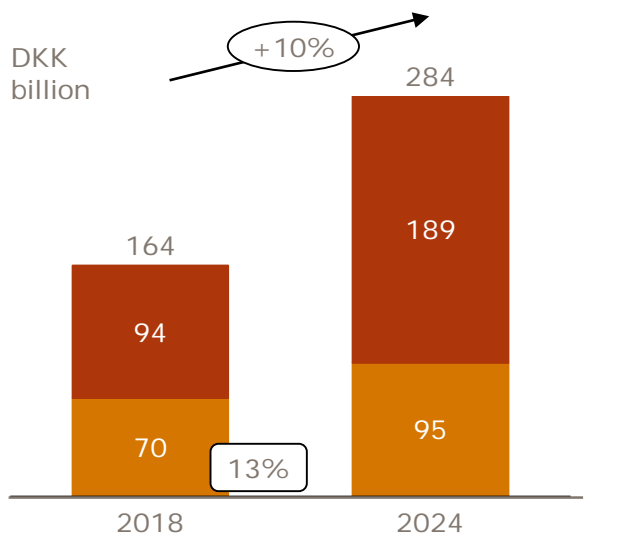


## Leveraging a deep disease understanding with NovoSeven®



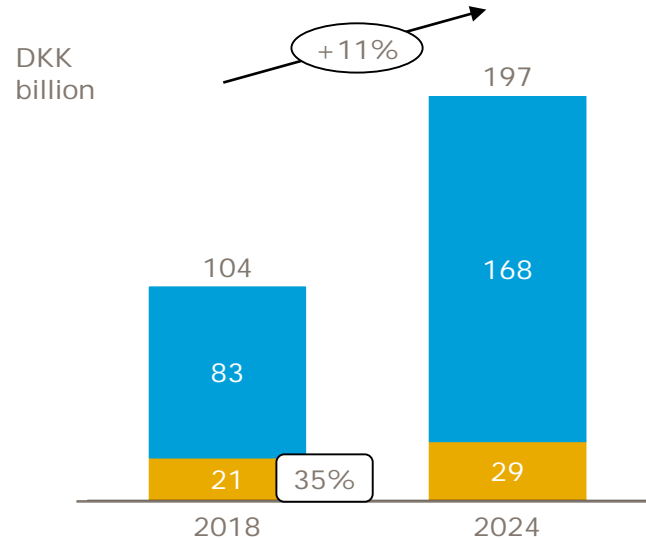
# Biopharm has a strategic path forward in rare blood disorders and rare endocrine disorders

Haemophilia market value  
Rare Blood Disorders market value



■ Haemophilia         Value market share  
■ Rare Blood Disorders         Annual growth rate

Growth hormone disorders market value  
Rare Endocrine Disorders market value



■ Growth hormone deficiency         Value market share  
■ Rare Endocrine Disorders         Annual growth rate

# Biopharm sustained growth outlook is supported by innovation and utilisation of core capabilities

## Internal and external innovation to drive long-term growth



Bringing **internal innovation** to market by pipeline progression



Ensuring future growth by leveraging **external innovation**

## Core capabilities within research and development to drive long-term growth



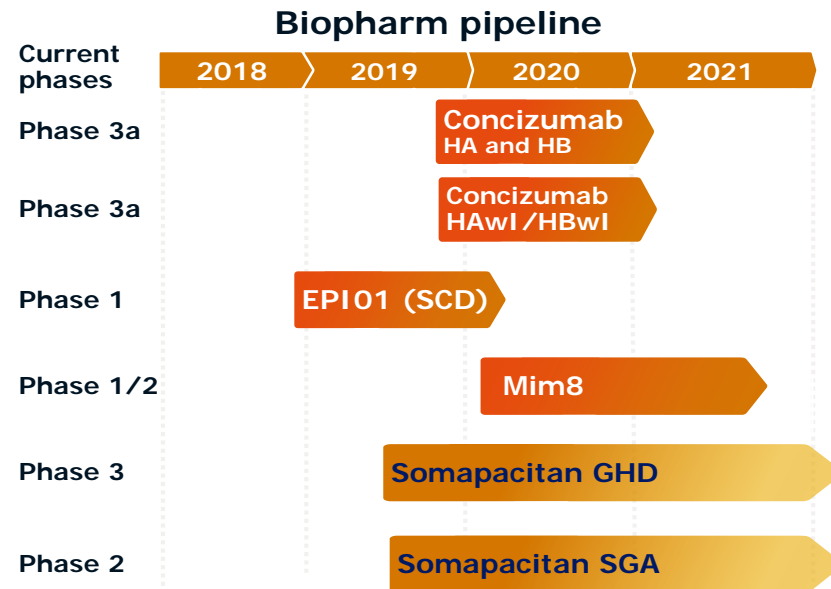
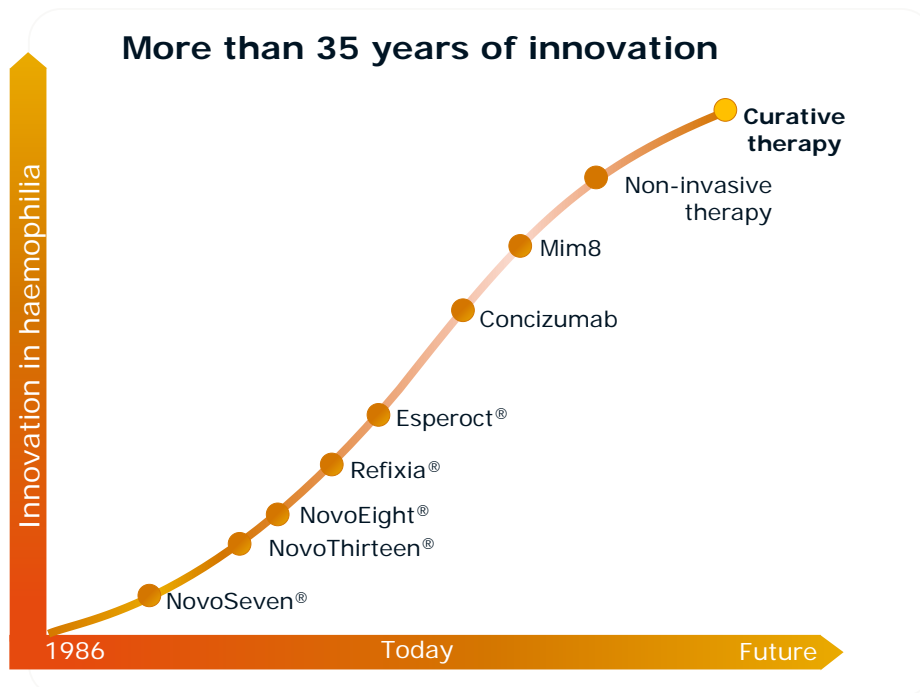
Exploring new technologies by utilising added **research platforms**



Leveraging deep **biological understanding** for future growth



# Scientific excellence ensures an innovative and competitive pipeline with therapeutic solutions for severe conditions



# Phase 3 initiated with concizumab for HA, HB with and without inhibitors

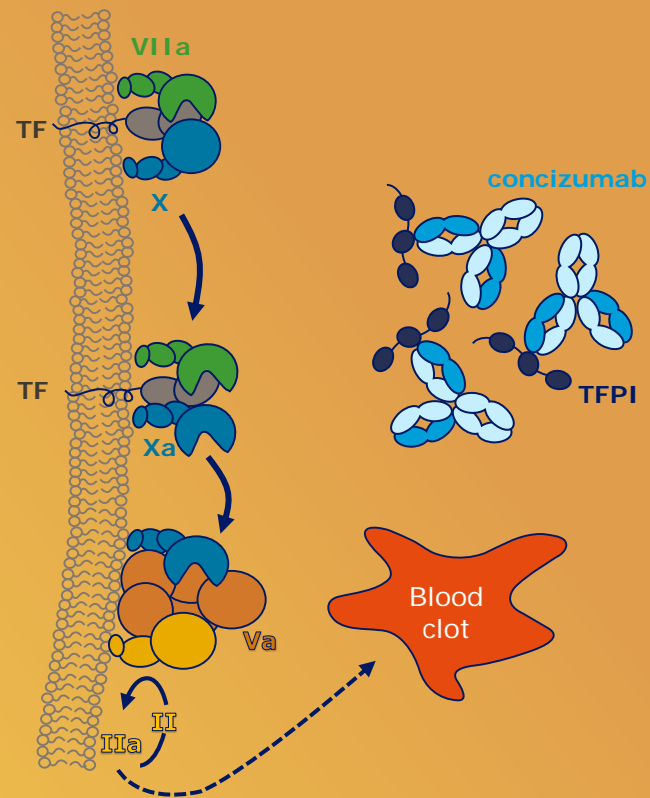
High affinity, humanised monoclonal IgG4 antibody

First-in-class anti-TFPI boosting the initiation phase to restore haemostasis

Delivered once-daily in a convenient **Flextouch®** pen

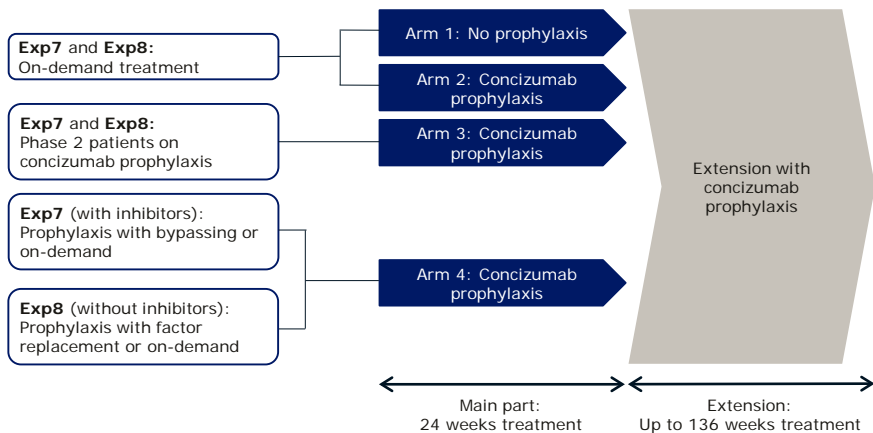
Safe and well-tolerated in phase 2 and efficacy comparable to factor replacement<sup>1</sup>

## Concizumab mode of action

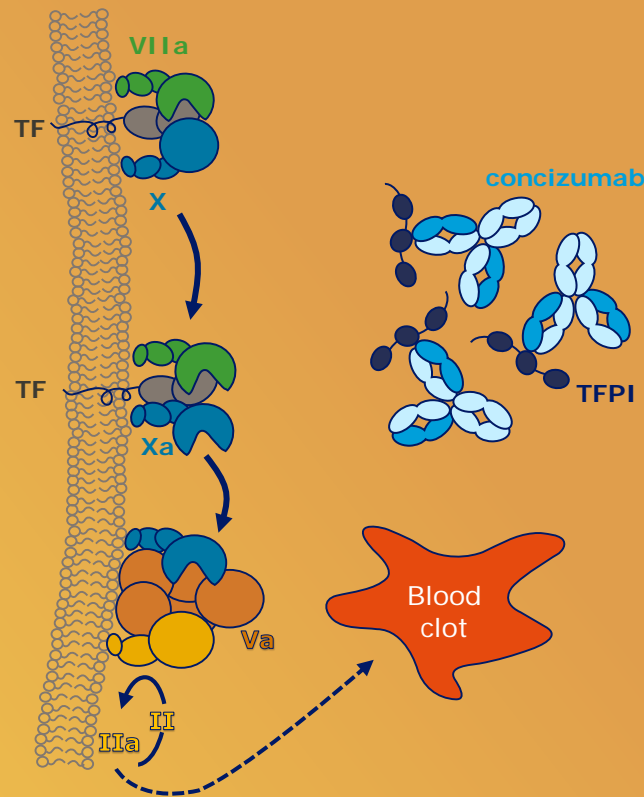


# Phase 3 initiated with concizumab for HA, HB with and without inhibitors

## Phase 3 trials with data expected first half of 2021

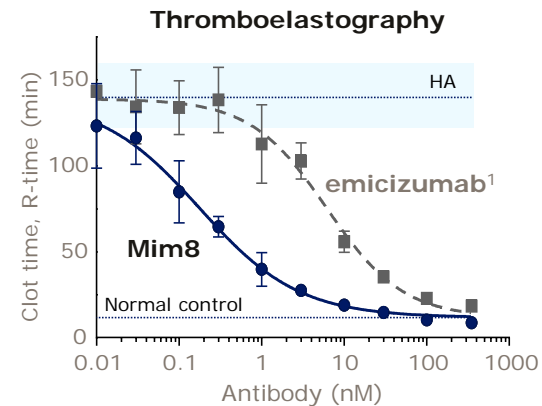
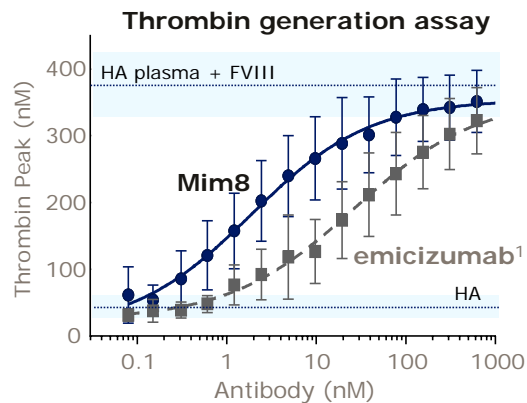
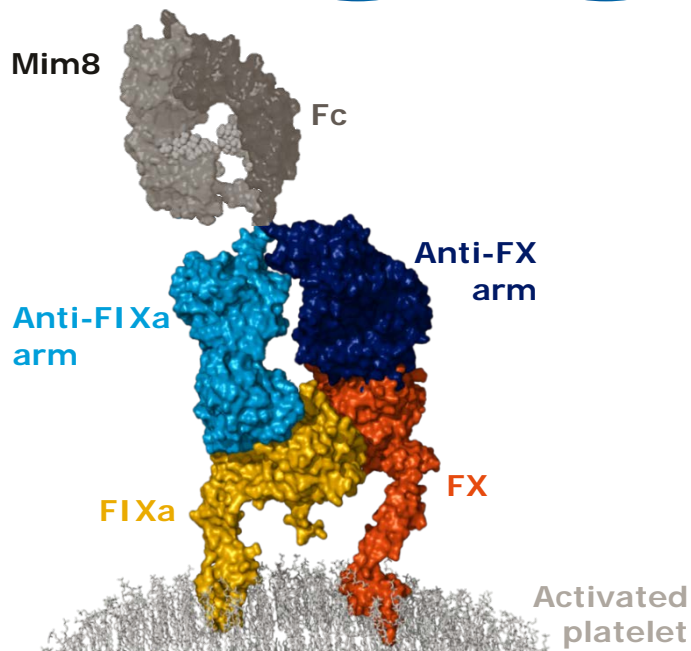


## Concizumab mode of action



# Next-generation FVIII mimetic, Mim8, is a bispecific antibody for subcutaneous prophylaxis treatment in people with haemophilia A

- Strong activity at site of bleeding
- Minimised target binding in circulation
- Delivered in an innovative device



**Mim8 potently stimulates FX activation** resulting in efficacious haemostasis *in vitro* and *in vivo*



**Mim8 effectively stops severe bleeds** in mouse models

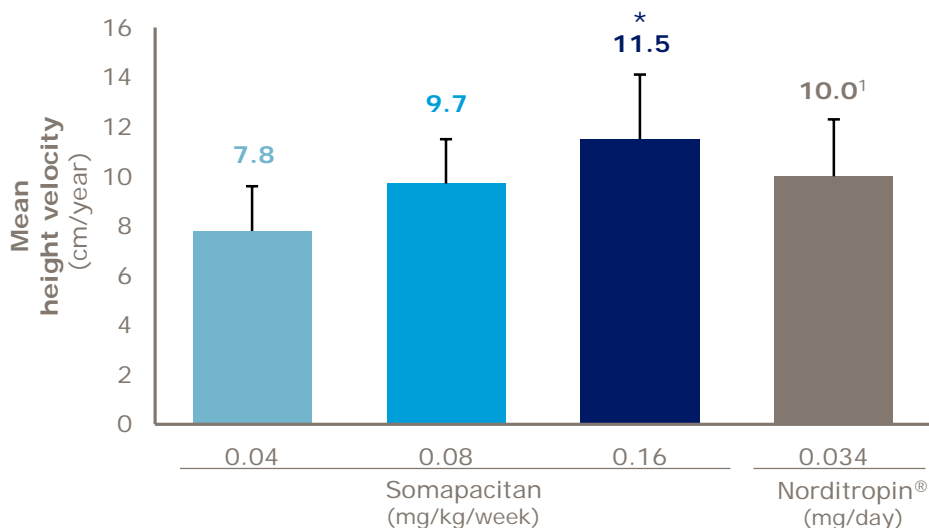


Phase 1/2 is expected to be **initiated H1 2020**

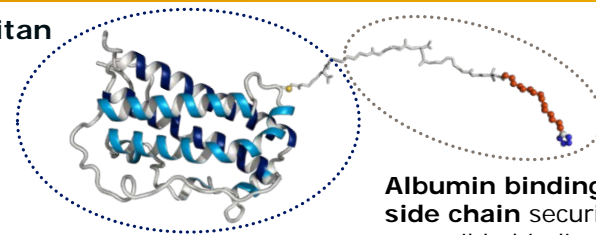
<sup>1</sup> Sequence-identical-analogue (SIA) of the FVIII-mimicking bispecific antibody emicizumab

# Once-weekly, biodegradable somapacitan has entered phase 3 for GHD and is filed with the US and EU regulators for AGHD indication

## Phase 2 trial in GHD with 1-year efficacy and safety



## Somapacitan



Growth hormone with a single amino acid substitution

Albumin binding side chain securing reversible binding to endogenous albumin

## Next steps

### Somapacitan in children (GHD)

- Phase 3 trial (REAL 4) has been initiated
- Somapacitan dose 0.16 mg/kg/week

### Somapacitan in children (SGA)

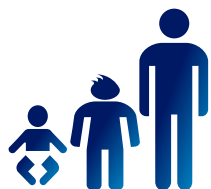
- Phase 2 trial (REAL 5) has been initiated

### Somapacitan in adults (AGHD)

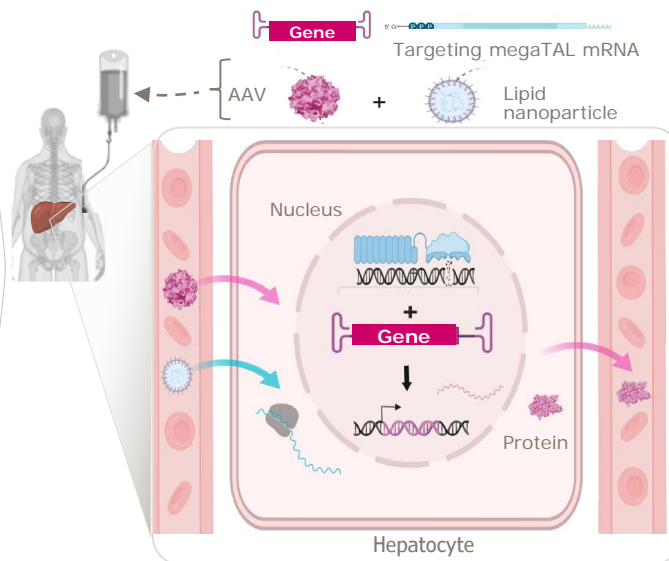
- Has been submitted in the US and the EU
- Japan submission planned for first half of 2020

# Novo Nordisk and bluebird bio join forces in next-generation genome editing for children and adult patients with haemophilia A

## Potential curative treatment in haemophilia A



- mRNA-based megaTAL™-driven gene editing
- **Highly specific and efficient** way to silence, edit or insert genetic components.
- Allows for **gene editing in all age groups**



## bluebird bio/Novo Nordisk's joint approach



- **megaTAL™**: Proprietary, patented technology, broad IP
- Correcting FVIII-clotting factor deficiency
- Potential **life long** effect
- Possibility to explore additional therapeutic targets

# Closing remarks



**Secure a sustained growth outlook for Biopharm** by leveraging commercial competencies and ensure frequent launches



**Strengthen and progress the Biopharm pipeline**

# Sources, notes and abbreviations – Biopharm

- **Slide 3:** Company reported sales; CER: Constant exchange rates
- **Slide 4:** Company reported sales, IQVIA, MAT value DKK, Sep 2019
- **Slide 5:** GHD: Growth hormone deficiency
- **Slide 6:** Company numbers for patient count
- **Slide 7:** Market size is based on EvaluatePharma, 2018. Market share for haemophilia is based on company reported sales. Market share for GHD is IQVIA, MAT, DKK, Sep 2019.
- **Slide 9:** Hwl: Haemophilia A or B patients with inhibitors; SGA: small for gestational age; GHD: Growth hormone deficiency
- **Slide 10:** Source: Hilden I, et al. Blood 2012, 1 Shapiro et al. Blood 2019. II: factor II; Iia: factor IIa; VIIa: factor VIIa; TF: tissue factor; TFPI: tissue factor pathway inhibitor; Va: factor Va; X: factor X; Xa: factor Xa; IgG4: immunoglobulin G4; Sc.: subcutaneous; HA: Haemophilia A; HB: Haemophilia B
- **Slide 12:** GHD: Growth hormone deficiency; AGHD: Adult growth hormone deficiency; SGA: Small for gestational age
- **Slide 13:** Data are mean height velocity (cm/year)  $\pm$  SD at week (wk) 52. Doses are mg/kg/time. \* Denotes statistical significance difference compared to once-daily Norditropin®. GHD: Growth hormone deficiency; AGHD: Adult-onset growth hormone deficiency. <sup>1</sup> Value was 9.8 for the full analysis set. Value of 10.0 is from a post-hoc analysis that excluded 4 visits of one patient who discontinued prematurely at week 6