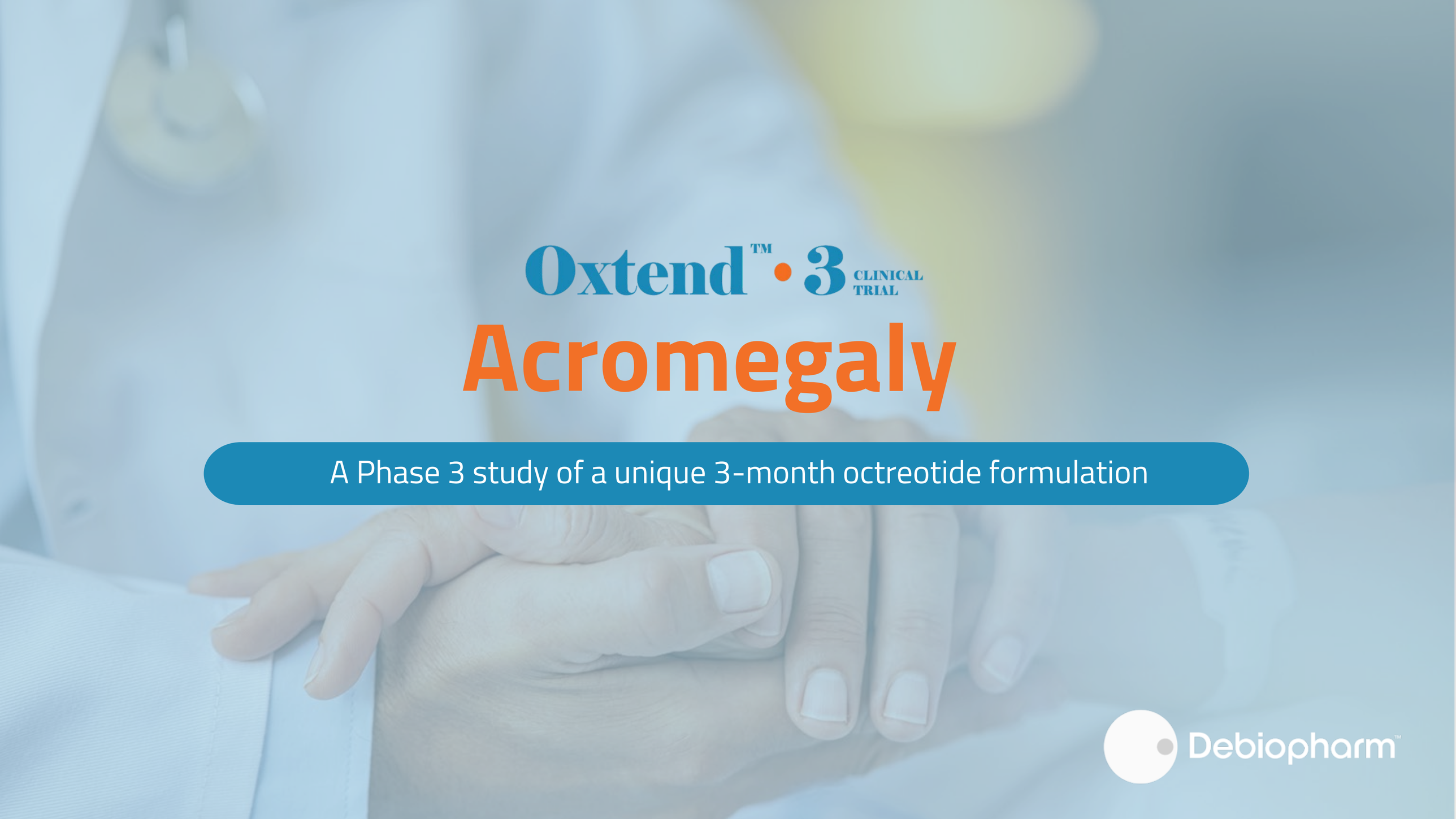

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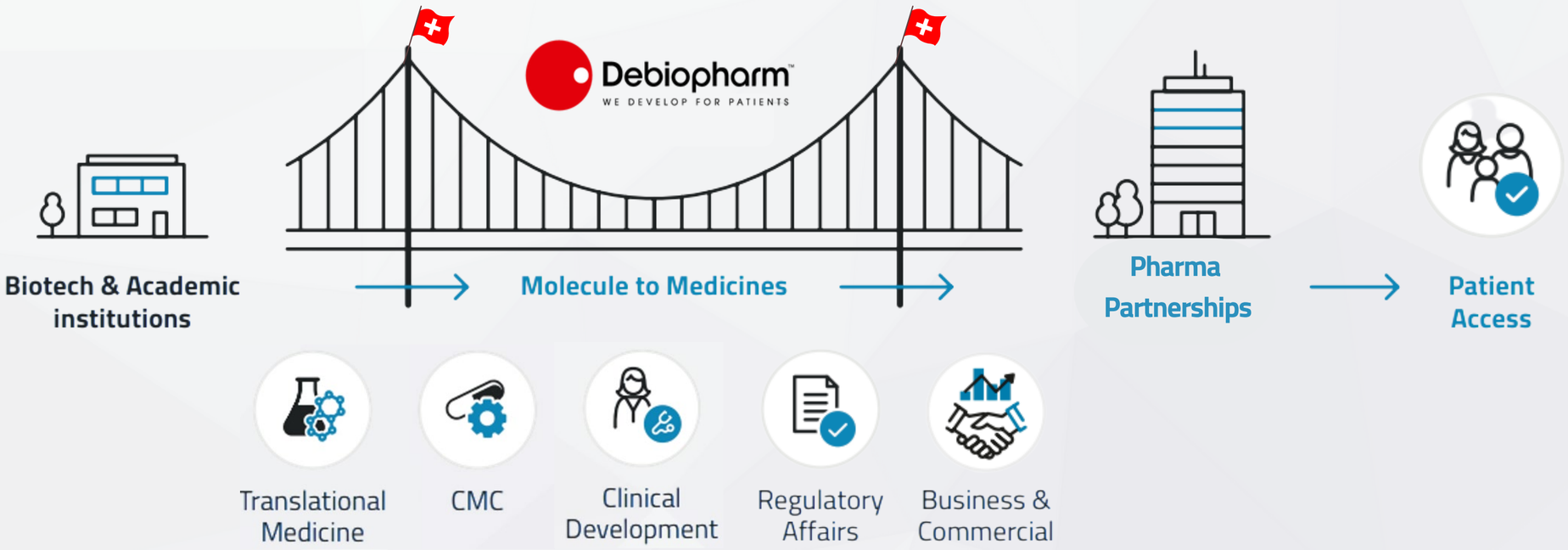
Acromegaly

A Phase 3 study of a unique 3-month octreotide formulation

Debiopharm™

Who We Are Since 40+ Years



CMC: Chemistry, Manufacturing & Controls

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Snapshot

Acromegaly

- Prevalence: ~**3–4 cases per million**
- Gender ratio: ~**1:1 (female : male)**
- Average diagnosis age: **40 years (males), 45 years (females)**
- Diagnosis delay: **5–15 years after symptom onset** (avg. 8.7 years)
- Key biomarkers: **Elevated GH & IGF-1**

ACROMEGALY COMMUNITY

"We have come a long way in the last 30 years but still have a far way to go, let's help patients live their best lives."

- Jill Sisco, President Acromegaly Community

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Source: Lavrentaki, A., et al. "Epidemiology of acromegaly: review of population studies." Pituitary, 2017; GH: Growth Hormone; IGF-1: Insulin-like Growth Factor-1

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Current Medical Treatment

SRLs/SSAs are the cornerstone of drug therapy

- Other options are reserved for second-line use.

Response and adherence vary

- Response rates can be as low as 55%, often requiring treatment switches.

Available dosing regimens are limited

- Only monthly injectables and daily oral options exist.

Debiopharm

Sources:
Maria Fleseriu et al. “A Pituitary Society update to acromegaly management guidelines“ Pituitary (2021) 24:1–13
Melmed, S., et al. "A Consensus Statement on acromegaly therapeutic outcomes." Nature Reviews Endocrinology, 2018.

SRLs: Somatostatin Receptor Ligands; SSAs: Somatostatin Analogs

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DEBIO SPHERE™ Technology

Decades of expertise

- Over 40 years of experience in controlled-release formulations.

Market Leadership.

- Leading different Therapeutic Area franchises with 1-, 3-, and 6-month sustained-release formulations, with a 12-month one in development.

Versatile & Reliable DEBIO SPHERE™ Platform

- Rapidly customizable long-acting release technology for sustained delivery of diverse molecules.

Convenience & adherence

- Efficacious and easier treatment through reduced dosing frequency.

Debiopharm®

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Debio 4126: The First & Only 3-Month Octreotide Formulation based on our DEBIO SPHERE™ Technology

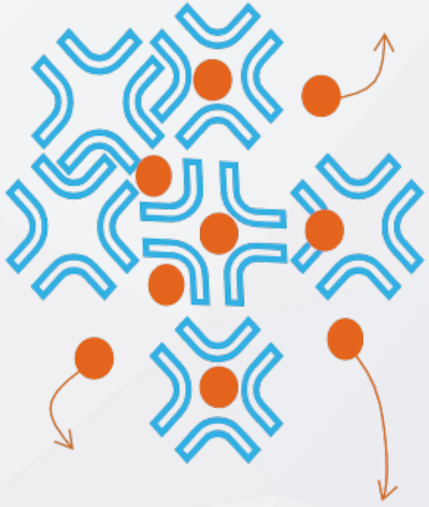
→ *Extended-release **ready-to-use suspension** for intra-muscular injection*

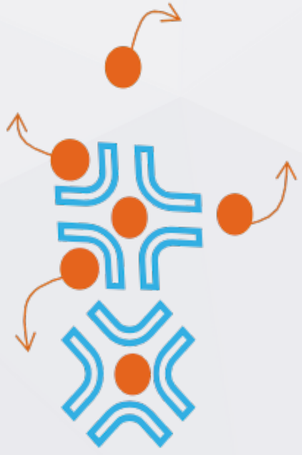
Active Ingredient

Octreotide

Excipient

PLGA





Hydrolysis releases active ingredient → *continuous release for 3 months*

Available dosage strengths:

30 mg – 60 mg – 90 mg

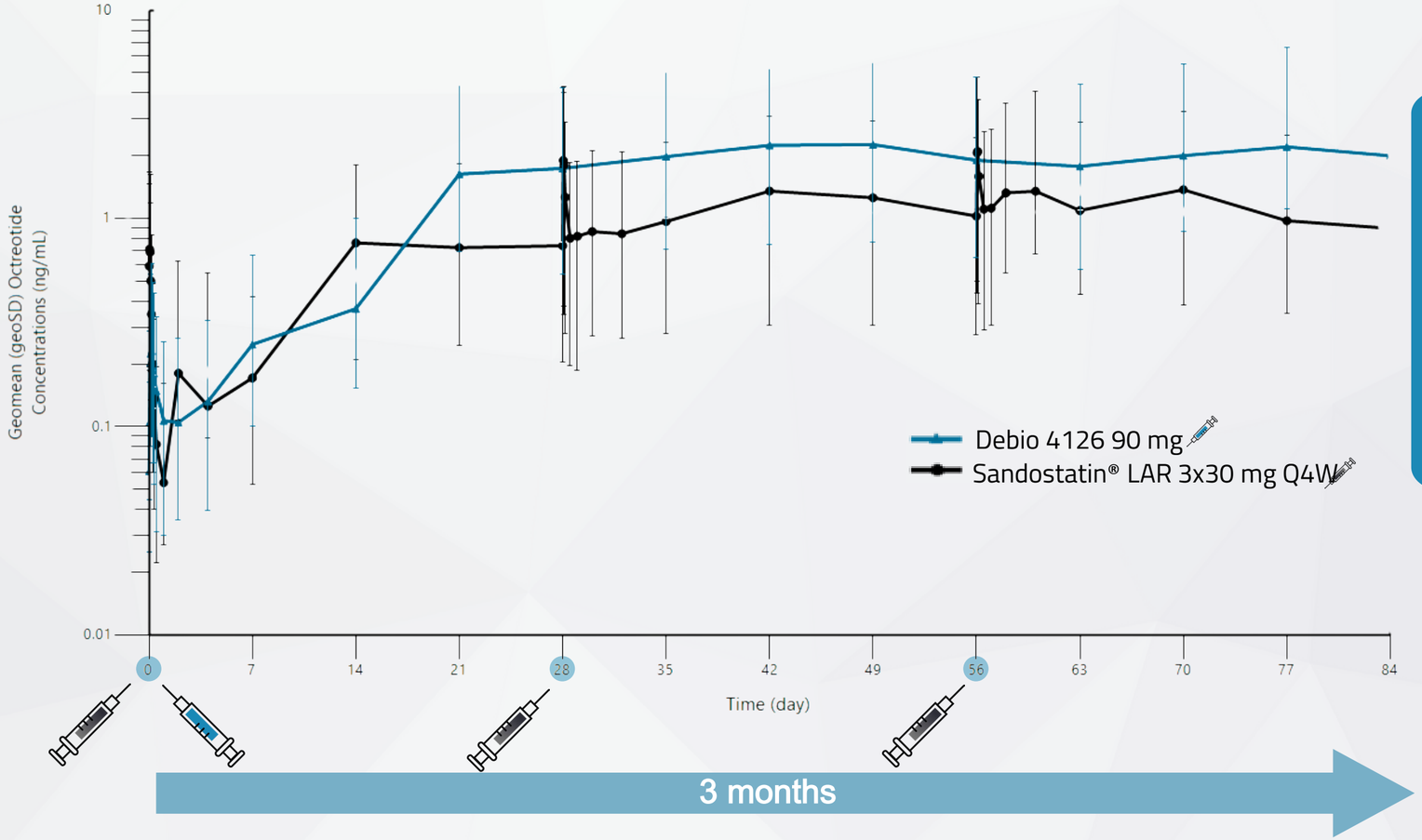
Corresponds to all three approved monthly octreotide dosages on the market.

Debiopharm®

PLGA: poly-lactic-glycolic acid (a completely biodegradable polymer)

PHASE 1 – Healthy Volunteers

DEBIO SPHERE™ Technology Provides Sustained Release Over 3 Months (Healthy Volunteers)



- **Sustained plasma levels:** Octreotide is released rapidly after dosing (0.5 hour), followed by sustained plasma levels for up to 84 days. (3 months)
- **Similar PK profile of 3 Sandostatin Injections:** Debio 4126 is comparable to the established monthly formulation.

Source: Data on file Debio 4126-101 study; LAR: Long Acting Release; PK: Pharmacokinetics; QW4: every 4 weeks; Sandostatin® LAR: octreotide acetate injectable suspension (Novartis Pharma AG)

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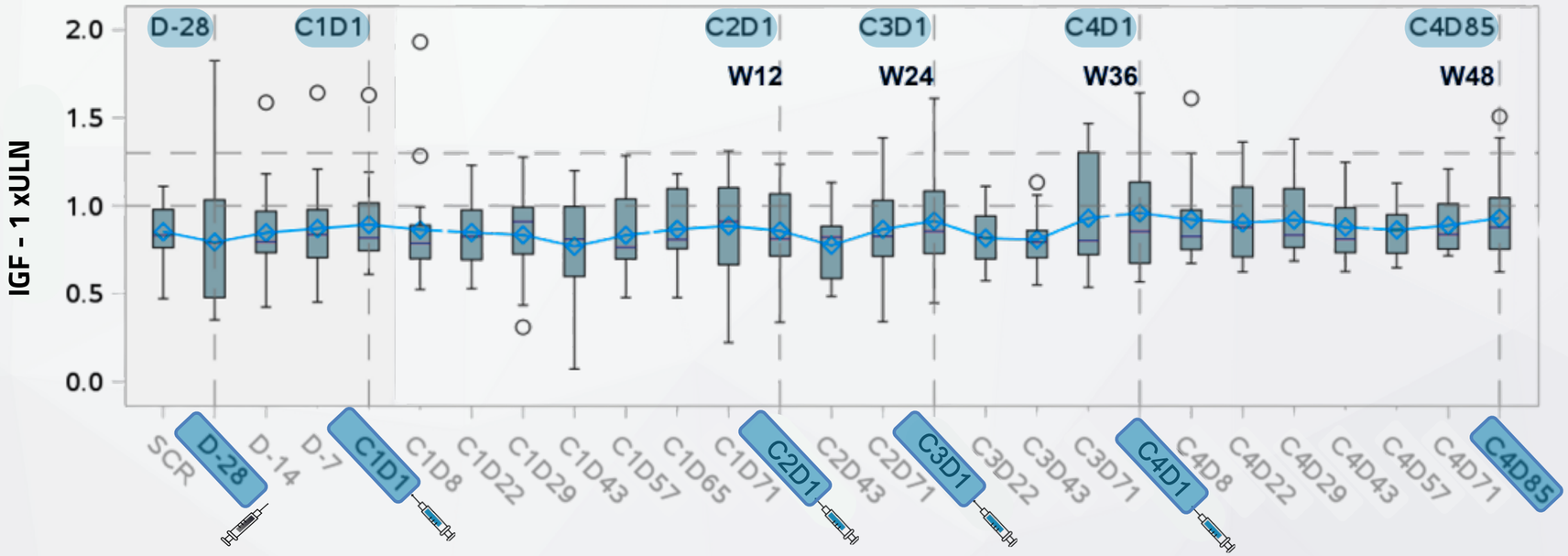
PHASE 1b – Patients with Acromegaly

Debio 4126 Maintains Baseline IGF-1 Levels in Controlled Patients with Acromegaly



Injection Experience

- **Smooth administration** from injectors' perspective
- **Well tolerated** by patients (VAS)
  - Local tolerability score in line with prior SSA
  - Injection-related pain in the Low range

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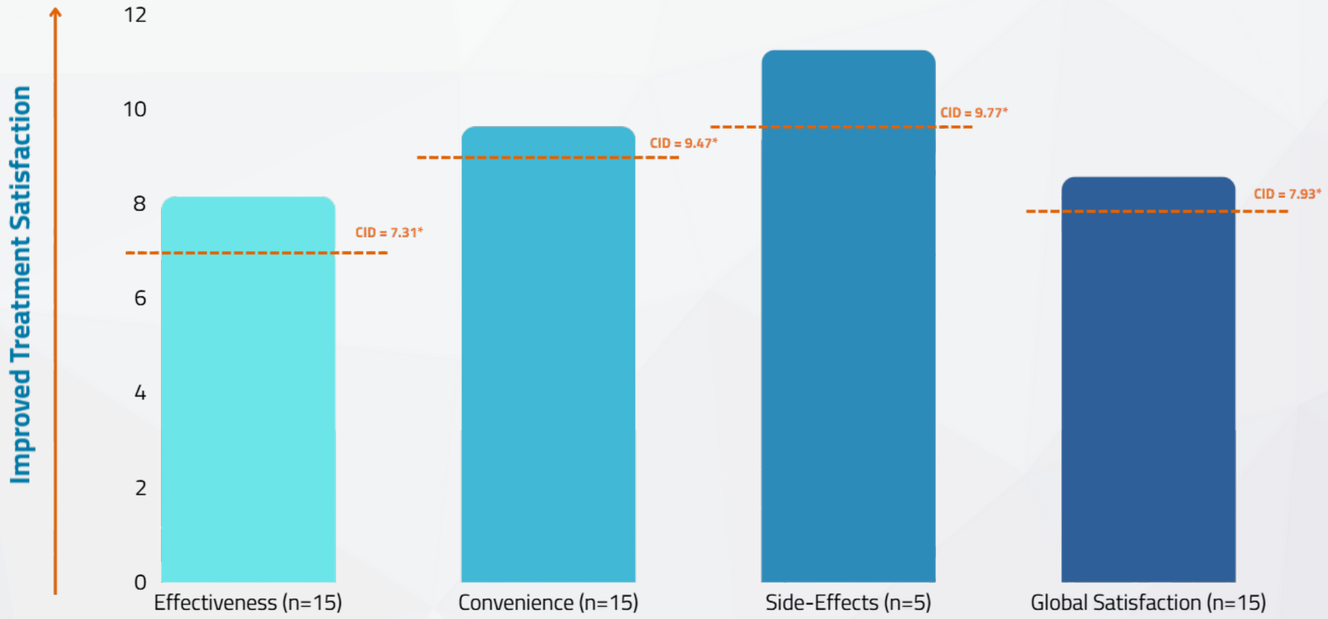
Source: Data on file Debio 4126-202 study NCT05364944; IGF1: Insulin-like Growth Factor 1; X ULN: "x" times the Upper Limit of Normal; VAS: Visual Analogue Scale

Oxtend™ 01

PHASE 1b – Patients with Acromegaly

Treatment Satisfaction Questionnaire for Medication (TSQM) Data - Improved Patient Satisfaction Over Time



Reduced Side-Effect Burden:

The number of patients reporting treatment-related side effects decreased consistently over time.

- Baseline = prior SSA: 50% (n=8)
- After 1st injection: 37.5% (n=6)
- After 3rd injection: 31.3% (n=5)

**CID: Clinically Important Difference, estimate calculated using distribution-based methods (i.e., ½ SD of baseline mean)*

Clinically Meaningful Improvement:

- By 3rd administration of Debio 4126, all TSQM domains and the Global Score showed a clinically meaningful improvement in patient satisfaction.

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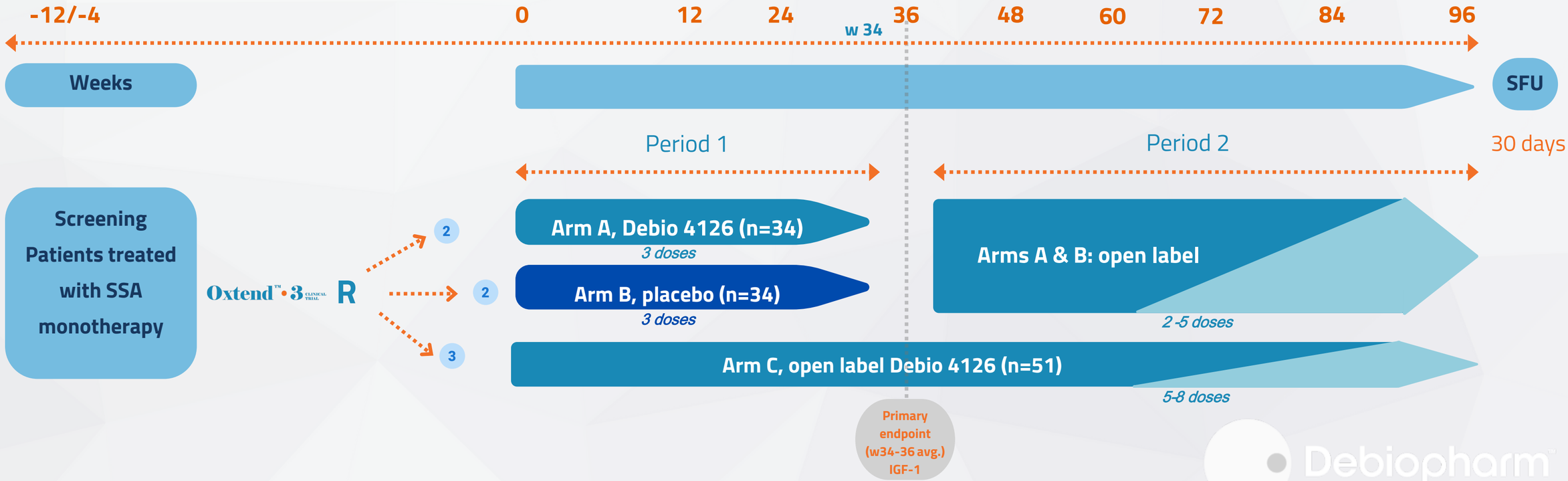
Source: Data on file Debio 4126-102 study. NCT05364944; TSQM: Treatment Satisfaction Questionnaire for Medication; SD: Standard Deviation

Oxtend™-03: A Phase 3 Study

A Clinical Trial in SSAs controlled Acromegaly Patients Switched to Debio 4126 (12-week dosing)



NCT06930625 *Source: Debio 4126-301 study; SSAs: Somatostatin Analogs;* ***R****: Randomization stratified by previous SSA dose; SFU: short-term follow-up;* IGF-1: Insulin-like Growth Factor-1;

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From 12 to just 4 injections per year

A Global Effort to Advance Acromegaly Patient Care

- 21 countries
- 73 selected sites
- 119 patients to recruit

Want to learn more about the clinical trial?

Scan the QR code *to contact*

Charlotte Catala-Goldschmidt, Clinical Trial Lead *directly via email: charlotte.catalagoldschmidt@debiopharm.com*

NCT06930625

Austria | Belgium | Brazil | Bulgaria | Denmark
Estonia | France | Germany | Hungary | Israel
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United States

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