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Debio 4126
Potential 1st and only 3-month product of Somatostatin Analogue (SSA)
Mar 2023

D-4126 Executive summary

The potential new SOC for treating Acromegaly and GEP-NET patients

- Unique opportunity to license a **novel Somatostatin Analogue (SSA) product** targeting **Acromegaly** and **Gastroenteropancreatic Neuroendocrine Tumours (GEP-NETs) with the potential of becoming the new SOC of treatments**
- **~$3B SSA** marketplace dominated by **2 existing 1st generation 1-month treatments**
- **The product** will be the **only 3-month SSA** for patients with **Acromegaly** and **GEP-NET**
- **Safe & effective** 3-month product which **reduce the number of injections from 12 to 4** per year leading to a decrease of medical resource utilization costs and patient treatment burden
- **Phase 1** healthy volunteers and **Phase 1b** patient studies ongoing - **Phase 3** in preparation
- **First approval for Acromegaly targeted in the USA** with potential **patent protection up to 2043**
- **Opportunity for partnership** to move the assets through development, registration and commercial launch

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SOC= Standard of Care

THE CHALLENGE & INDICATIONS

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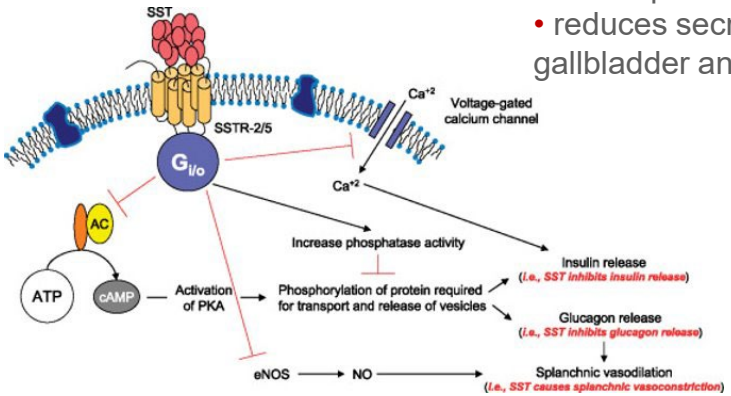
Somatostatin: key facts

- **Endogenous peptidic hormone that regulates the endocrine system and affects neurotransmission and cell proliferation**
  - acts via G protein-coupled somatostatin receptors (sst1-sst5)
  - inhibits secretion of many hormones: gastrin, CCK, glucagon, insulin, hormones from anterior pituitary (e.g. **GH**), TSH, VIP, etc
  - reduces secretion of fluids by intestine and pancreas, inhibits contraction of the gallbladder and reduces gastrointestinal motility



- **Somatostatin receptors are an important pharmacological target for some neuroendocrine diseases, such as:**
  - Acromegaly
  - Gastro-entero-pancreatic Neuroendocrine tumours (GEP/NET)
  - Polycystic liver disease (potential additional indication for D-4126)

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D-4126 Indications

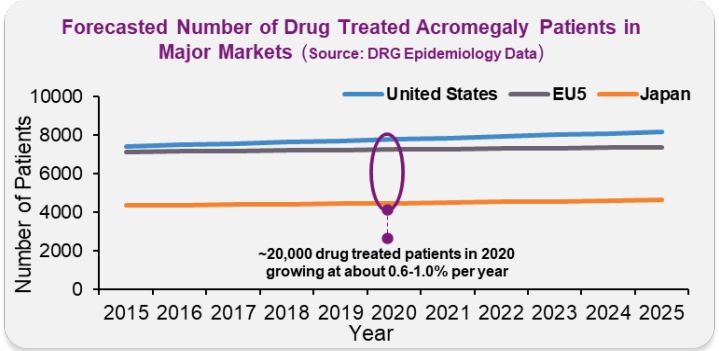
Acromegaly: key facts

ACROMEGALY

Disease overview

Acromegaly is a **rare** debilitating **disease** with slowly developing symptoms and varied presentation

- **Age of diagnosis:** mean age is 40y in males & 45y in females
- **Delay in disease diagnosis**: gap between symptoms onset to diagnosis is 5-15 years (mean gap of 8.7 years)
- **Key parameters for diagnosis**: excess of GH and IGF-1 levels



Pharmacological therapy

- **Life-long pharmacological therapy required** by **~40-50%** patients to control the disease
- **SSAs** (Octreotide - Novartis or Lanreotide - IPSEN) **are first line of pharmacological treatment**
- **SSAs have been tried and tested for over 20 years and physician experience and confidence in this class is very high**
- Goals of treatment of acromegaly **are normalization of biochemical abnormalities, attenuation of symptoms, control of tumor mass, maintenance of pituitary function and reduction of mortality** (Katznelson et al 2014). **Octreotide was shown to act on all of those**
- **Treatment monitoring is based on IGF-1 level** & failure to suppress IGF level is an indicator for switching to next line of therapy

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D-4126 Indications

GEP-NET: key facts

GEP-NET

Disease overview

- **GEP-NETs: ~ 30-40% of all NETs**
- Heterogeneous group of rare neoplasms with variable clinical evolution; Most are slowly-growing malignant tumours, and have metastases already at diagnosis
- **>80% GEP-NETs express SSTR2**, an SSA target

Pharmacological therapy

- **~50% of patients** diagnosed with GEP-NET receive pharmacological treatment
- **First line pharmacological treatment: SSAs** with dual benefits.
- **SSAs** have **antiproliferative activity** and **control symptoms specific to carcinoid syndrome**
- Patients are on SSAs for **2-3 years before progression, then they may continue SSAs in combination with other therapies**

GEP-NET Treatment with SSA

SSAs are the 1st line pharmacological treatment in all patients with GEP-NET

Non-Functioning (70%) *The most common presentation is nonspecific abdominal pain*	›	**Antiproliferation:** Somatostatin analogues
Functioning (30%) *Present symptoms of the excess hormones they produce*	›	**Antiproliferation:** Somatostatin analogues **Symptomatic Treatment:** Somatostatin analogues

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THE MARKET

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Somatostatin Analogues

Market: key facts

- The Global **SSAs Market is estimated at ~$3B** with 2 major historical players (Novartis and IPSEN) marketing **1-month formulations only**

- **USA is the biggest market** (~58% of global sales) with a **growth of 10% YoY**
  - **Sandostatin LAR** (Octreotide - Novartis) is still the market leader in volume but **Somatuline** (Lanreotide - IPSEN) is faster growing product and leader in value
  - **Convenience-based factors** drive treatment choice significantly

- **Indication split** is **~60% in GEP-NETs**, **~30% in Acromegaly** and ~10% in others
  - Number of patients in both indications is increasing each year (earlier diagnosis & increasing prevalence)

- **Generics / Hybrids / new entries** with 1-month products and BID oral formulation available with no big signs of disruption in market value

VALUE PROPOSITION

D-4126

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Value proposition

Debio 4126: potentially the 1st and only 3-month product of SSA

- **Differentiated product vs. current SOCs in both Acromegaly and GEP-NET**
- **Debio 4126 vs. current SOC**
  - Increase convenience for patients: **only 4 injections/year**
  - Sustained 3 months Octreotide release at appropriate drug levels
  - Sustained inhibition of IGF-1 and Safety profile in healthy volunteers consistent with marketed SSAs
- **First approval for Acromegaly targeted in the USA** with potential **patent protection up to 2043**
- **Debiopharm, proven track record in developing** polymer-based, **sustained-release** injectables.

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Value Proposition

Debio 4126: key facts

LARGE MARKET POTENTIAL

SSA market ~$3B

Potential new SOCs

QUICK PATH TO MARKET IDENTIFIED

First approval in Acromegaly in USA

EXPECTED PATENT PROTECTION

Potentially up to 2043

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Thank you
for your attention

Do you have any questions?

We are keen to further discuss this opportunity and share in depth info after a signed CDA is in place

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