

July 2025 | Euronext: ALBPS – OTC: BPTSY



Forward Looking Statements



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A clinical-stage biotechnology company specialized in the development of therapeutics for muscular and metabolic diseases

LIVE HEALTHIER LONGER

Aging, when combined with obesity, are main factors of age-related diseases, disabilities and finally reduced longevity. Biophytis has been leveraging a biology of aging platform with Sorbonne University to develop drug candidates for age-related diseases. It's most advanced drug candidate BIO101 is a potential first-in-class small molecule that stimulates muscle anabolism and is in clinical development for sarcopenia and obesity.



HQ location: Paris, France

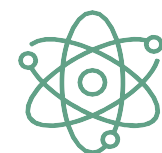
Other locations in Sao Paulo, BR
and Cambridge, MA US



Founded:
2006



Euronext growth Paris (ALBPS)
OTC market (BPTSY)



Drug discovery: biology of aging for
developing drugs for age-related diseases



Multiple partnerships

**Academical
partnerships**



**Pharmaceutical
partnership**





A clinical-stage biotechnology company specialized in the development of therapeutics for **muscular and metabolic diseases**

KEY UPCOMING MILESTONES

Biophytis is entering a decisive phase in the clinical development of its lead drug candidate, BIO101, with **major upcoming milestones in both obesity (OBA program) and sarcopenia (SARA program)**. Over the next 18 months, the company is preparing to **initiate new Phase 2 and Phase 3 studies**, while continuing to strengthen its international partnerships and regulatory positioning.



OBESITY MILESTONES

Q2 25: BIO101 + GLP-1 animal studies results

Q3 25:

- Readiness to start phase 2 clinical study in obesity OBA in the US
- First patient-in in the US

Q4 25:

- Readiness to start phase 2 OBA clinical study in Brazil & EU
- First patient in In EU & Brazil

H1 26: Last patient in and out

H2 26: Reporting of the results



SARCOPENIA MILESTONES

Q2 25: Exclusive discussion for licensing-out BIO101 with a large Chinese pharma

Q3 25: Preparation to start Phase 3 SARA study with partner in China and Europe

Q4 25:

- Production of clinical batches
- Regulatory approval in China

H1 26:

- Readiness to start phase 3 SARA clinical study
- First patient-in in EU



BIOPHYTIS' People: Expertise & Passion



Stanislas VEILLET
CEO, cofounder



Jean MARIANI
Chief Medical Officer



Pierre DILDA
Chief Scientific Officer



Edouard BIETH
Chief Strategy Officer



Waly DIOH
Chief Operations Officer



Chiara BACCELLI
Chief Pharmaceutical Operation,
Officer & Quality Assurance Director



Christophe COURTILLAT
Chief Financial Officer



BIO101 (20-hydroxyecdysone): Potential first-in-class drug candidate

New molecular target

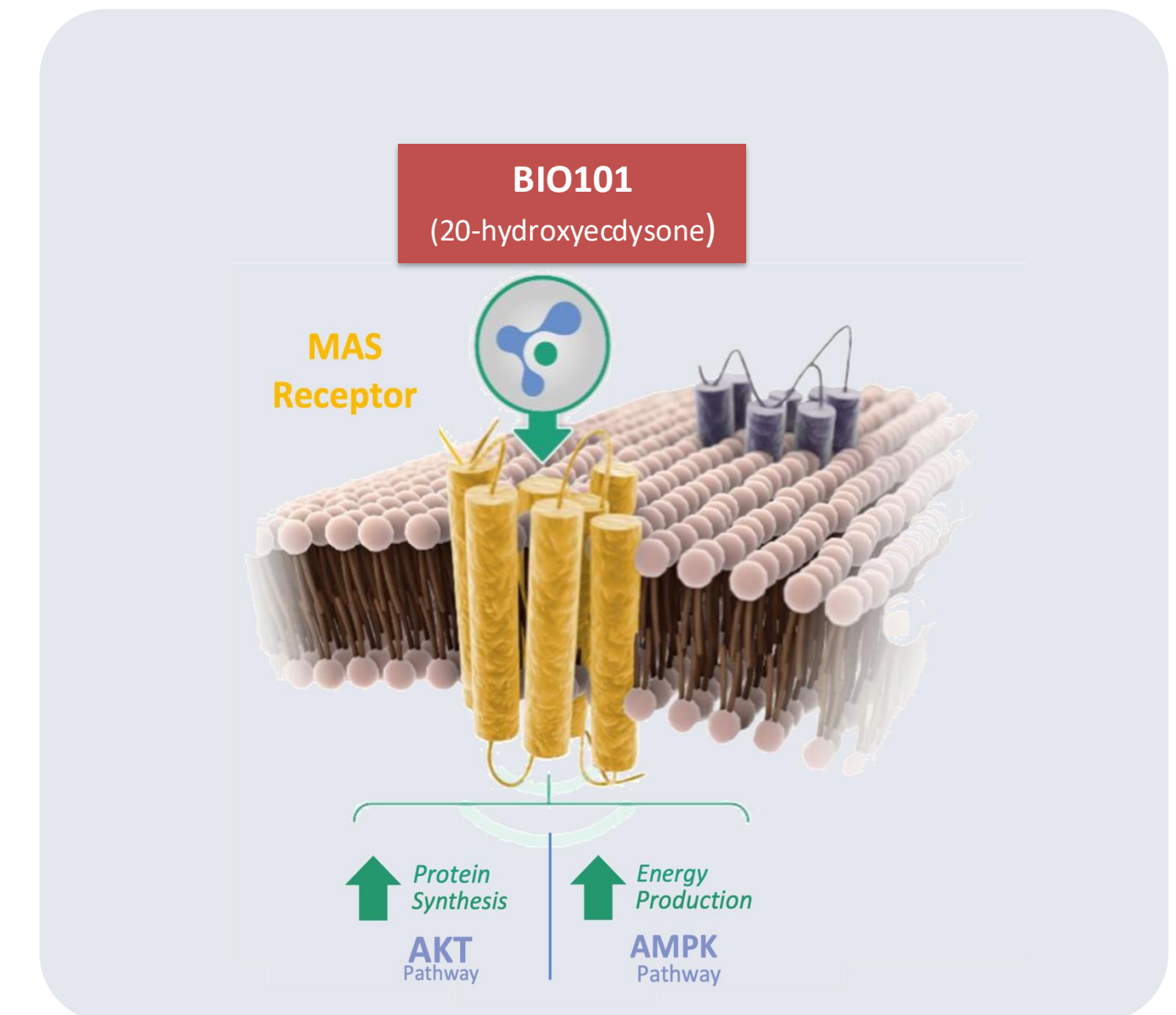
- Activation of MAS receptor¹ (renin-angiotensin system)
- Regulation of smooth, cardiac and skeletal muscle metabolism
- Stimulation of muscular and respiratory functions

POC & safety in clinical studies

- Completed clinical studies in healthy elderlies and obese adults (Phase 1)
- Completed clinical study in sarcopenic & obese sarcopenic elderlies (Phase 2)

Convenience, affordable manufacturing cost and a robust IP

- 14 patent families, 44 patents granted in key western (US, EU, Japan) and BRICS (China, BR) countries
- 5 patent families covering specifically sarcopenia & obesity indications
- API manufactured at industrial scale for an oral intake



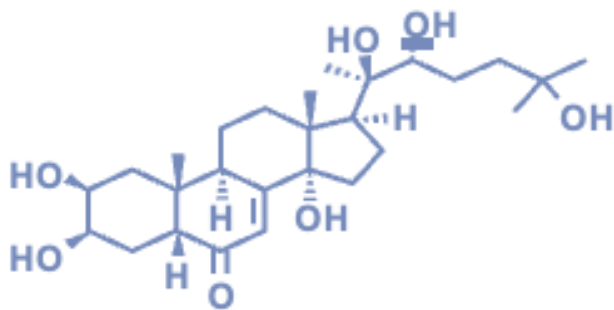
BIO101 (20-hydroxyecdysone) activates MAS receptor and triggers downstream two signaling-pathways in myocytes: AKT & AMP (based on molecular and cellular models)



Our Clinical Pipeline



A unique development program for improving mobility

Biophytis is preparing to initiate the **Phase 2 OBA study in obesity in 2025** and the **Phase 3 SARA study in sarcopenia by 2026**.

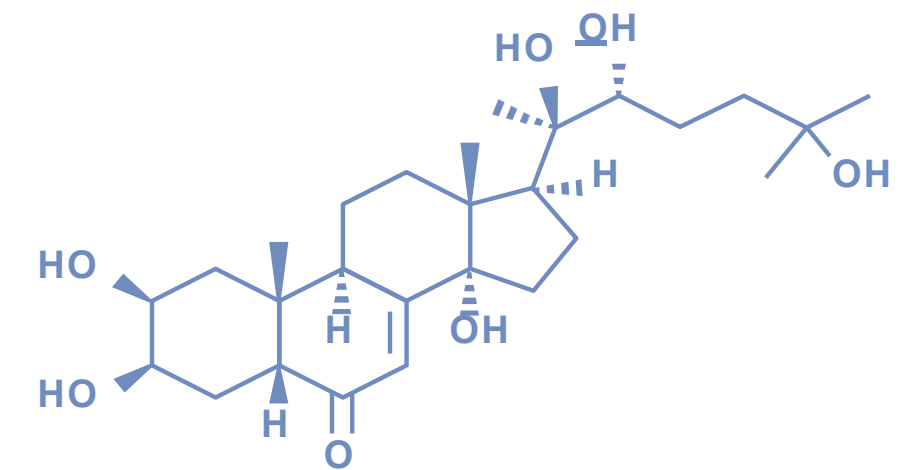


Candidate	Indication	Program	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory	Market
BIO 101 20-hydroxyecdysone	Sarcopenia							
	Obesity							

BIO101 is designed to address major public health challenges, notably **Obesity and Sarcopenia**, and unlock huge market opportunities



BIO101 represents a potential breakthrough in the treatment of muscle-related diseases. Its unique mechanism of action targets muscle function and muscle structure, to address two critical public health challenges :



BIO101 (20-hydroxyecdysone)



Obesity significantly impairs mobility, while current obesity treatments (GLP1) can potentially cause further muscle wasting.

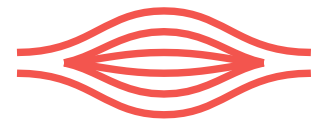


Sarcopenia is characterized by the degenerative loss of muscle mass, quality, and strength – no therapeutic solution exists today for treating sarcopenia

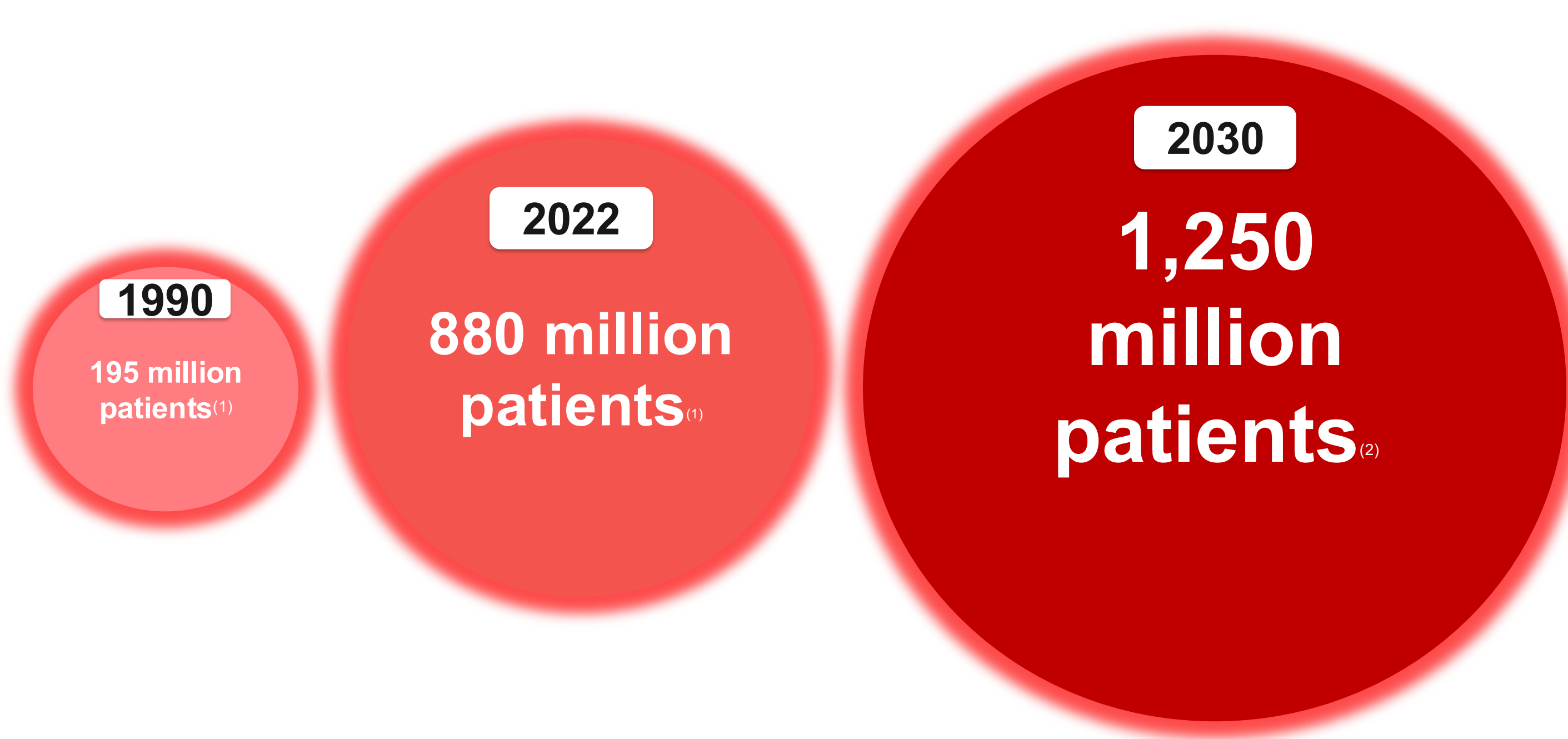
BIO101 (20-hydroxyecdysone)

in Obesity





Obesity : an uncontrolled global epidemic and a huge market opportunity



\$4tn

The global cost of treating obesity-related complications by 2035.

3x

The global prevalence of obesity has more than tripled since 1975.

\$100bn

MARKET SIZE BY 2030

Global number of obese patients among the adult population



Obese patients have poor muscle quality and suffer from reduced mobility



96%

of obese patients have **impaired specific muscle strength** ⁽¹⁾



84%

of obese patients are deemed to have **poor muscle quality** ⁽¹⁾

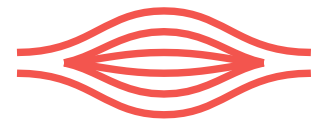
“

In clinical practice, **caregivers should consider strategies to**
maintain muscle
status when applying surgical or pharmacological obesity management therapies ⁽²⁾

nature International Journal of Obesity

”





Muscle wasting: an unmet medical need



Semaglutide at its weight loss dose of 2.4 might have a potentially worse lean mass loss ratio. In the Ph3 trial STEP-1, semaglutide showed less optimal 1.98-to-1 ratio of fat-to-lean mass loss on a percentage basis (1.50-to-1 on an absolute basis, at week 68 Wilding et. al JES 2021 and Wilding et. al. NEJM 2021).



Tirzepatide in obese patients was said to be “similar to that reported with lifestyle-based and surgical treatments for obesity,” (Jasteboff et. al. NEJM 2022). In the Ph3 SURMOUNT-1 trial, tirzepatide showed a 3.11-to-1 ratio of fat-to-lean mass loss on a percentage basis (week 72, absolute basis not reported Jasteboff et. al. NEJM 2022).

**Up to 40% of
muscle loss**

**Proportion of lean body mass loss
vs total weight loss in obese
patients treated with GLP-1RA.**

**And no drug registered for preserving
muscle mass and/or function in case of
obesity management with GLP1-RAs**

High medical need to be converted into a huge market opportunity



Sources:




World Obesity Federation report: <https://www.worldobesity.org/news/economic-impact-of-overweight-and-obesity-to-surpass-4-trillion-by-2035>

World Health Organization report: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>

McCarthy et al. Weight Loss Strategies and the Risk of Skeletal Muscle Mass Loss. Nutrients 2021, 13, 2473: <https://doi.org/10.3390/nu13072473>



BIO101 is the only muscle agent in clinical development focusing on muscle strength

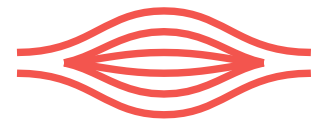
Drug	Company	Mode of action	Main Effect	Safety & Side effects	Administration route	Status
BIO101		MAS Receptor activator	Muscle strength (<i>knee extension determined by dynamometry</i>)	BIO101 has been well tolerated in 277 individuals across multiple clinical studies	Oral	Phase 2
Azelaprag	BIOAGE	APJ agonist	% change in overall weight loss	Hepatotoxicity (Liver transaminitis) (5)	Oral	Phase 2 halted
Bimagrumab		Activin type II receptor blocker	Changes in body weight, waist circumference, and body composition	Muscle spasms and diarrhea (2)	Intravenous	Phase 2
Enobosarm		Selective Androgen Receptor modulator	Total lean body mass	Increased hepatic transaminases, fatigue, hypercalcemia (1)	Oral	Phase 2 completed



There is no drug registered for muscle preservation in obesity



Source: (1) Lancet Oncol 2024; 25: 317–25 (2) JAMA Network Open. 2020;3(10):e2020836. doi:10.1001/jamanetworkopen.2020.20836 (4) DrugBank entry on Trevogrumab (5) <https://bioagelabs.com/azelaprag>



Potential attributes of BIO101 (20-hydroxyecdysone) in obese patients treated with GLP-1RA



Effects on muscle wasting:

- Preservation of muscle strength
- Reduction of muscle mass loss
- Improvement of mobility



Effects on fat tissues:

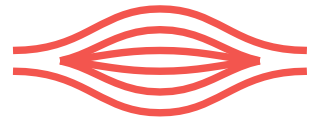
- Increase of fat mass loss



Convenient and safe administration :

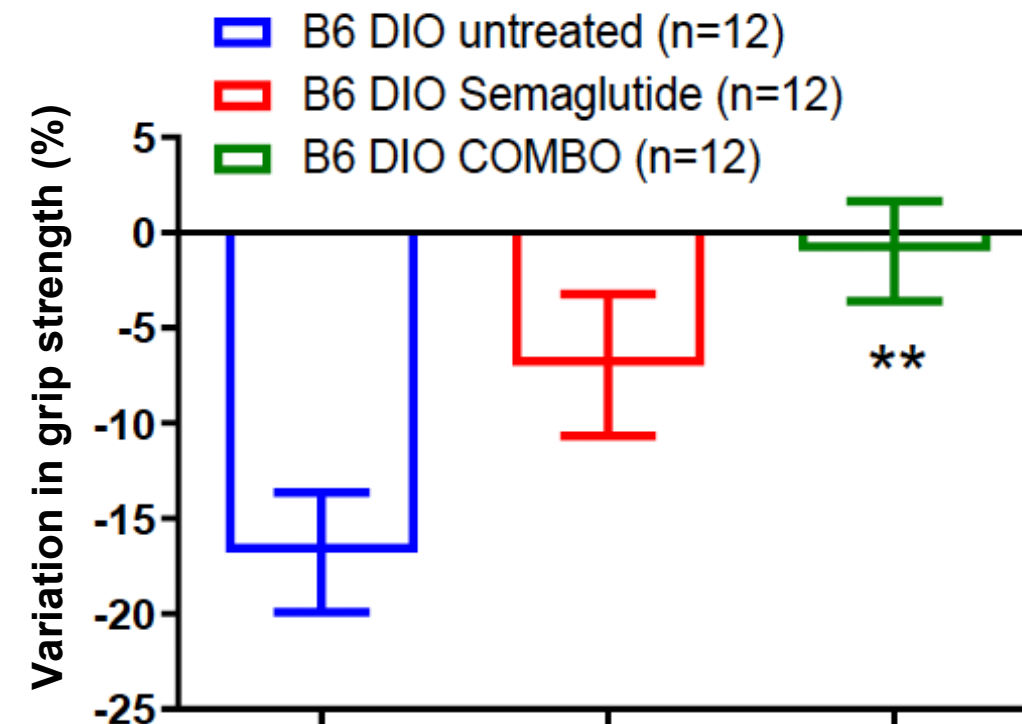
- Oral route
- Adequate safety observed to date in adults from trials in healthy volunteers (phase 1), in sarcopenia (phase 2) and Covid-19 (phase 2-3)



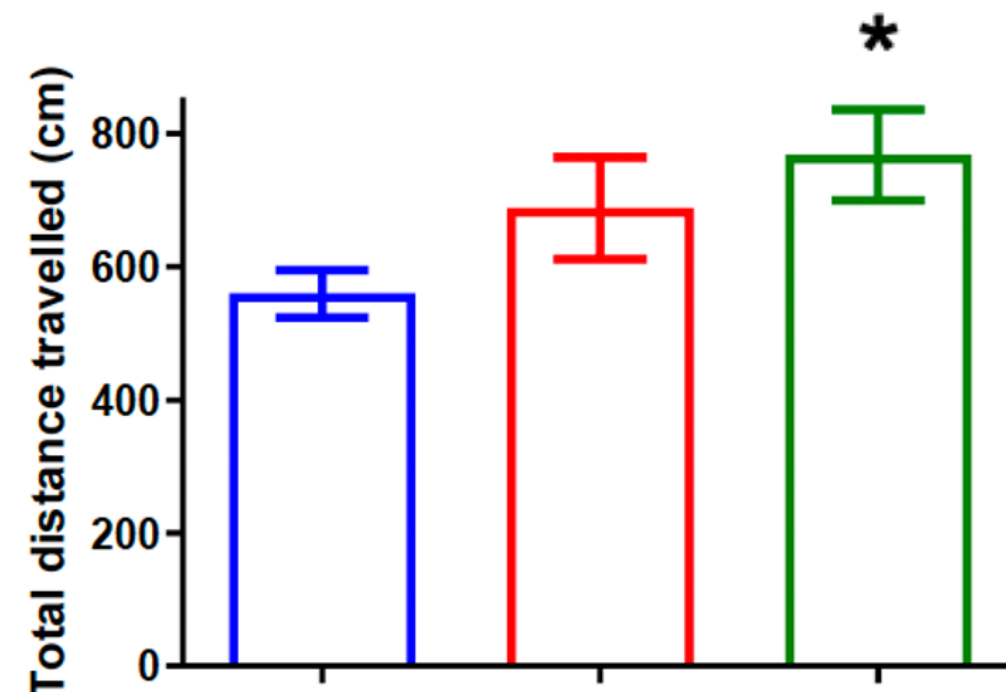


Revolutionary preclinical data in obesity

Grip test (strength)



Spontaneous activity



Metabolic effects in obese mice :

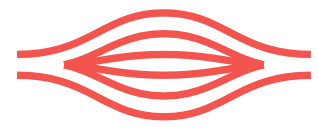
- Protective effect of BIO101 (20-hydroxyecdysone) in mice fed an obesity-inducing high-fat diet, preventing adipose tissue development
- Anti-obesity effect by increase in energy expenditure

Muscle function in mice fed high fat :

- Improved physical performances in adult and old animals orally treated with BIO101 (20-hydroxyecdysone)

Muscle function and mobility in obese mice treated with a GLP-1 receptor agonist:

- Protection of muscle strength and improvement of mobility in animals receiving a GLP-1 receptor agonist and orally treated with BIO101 (20-hydroxyecdysone).

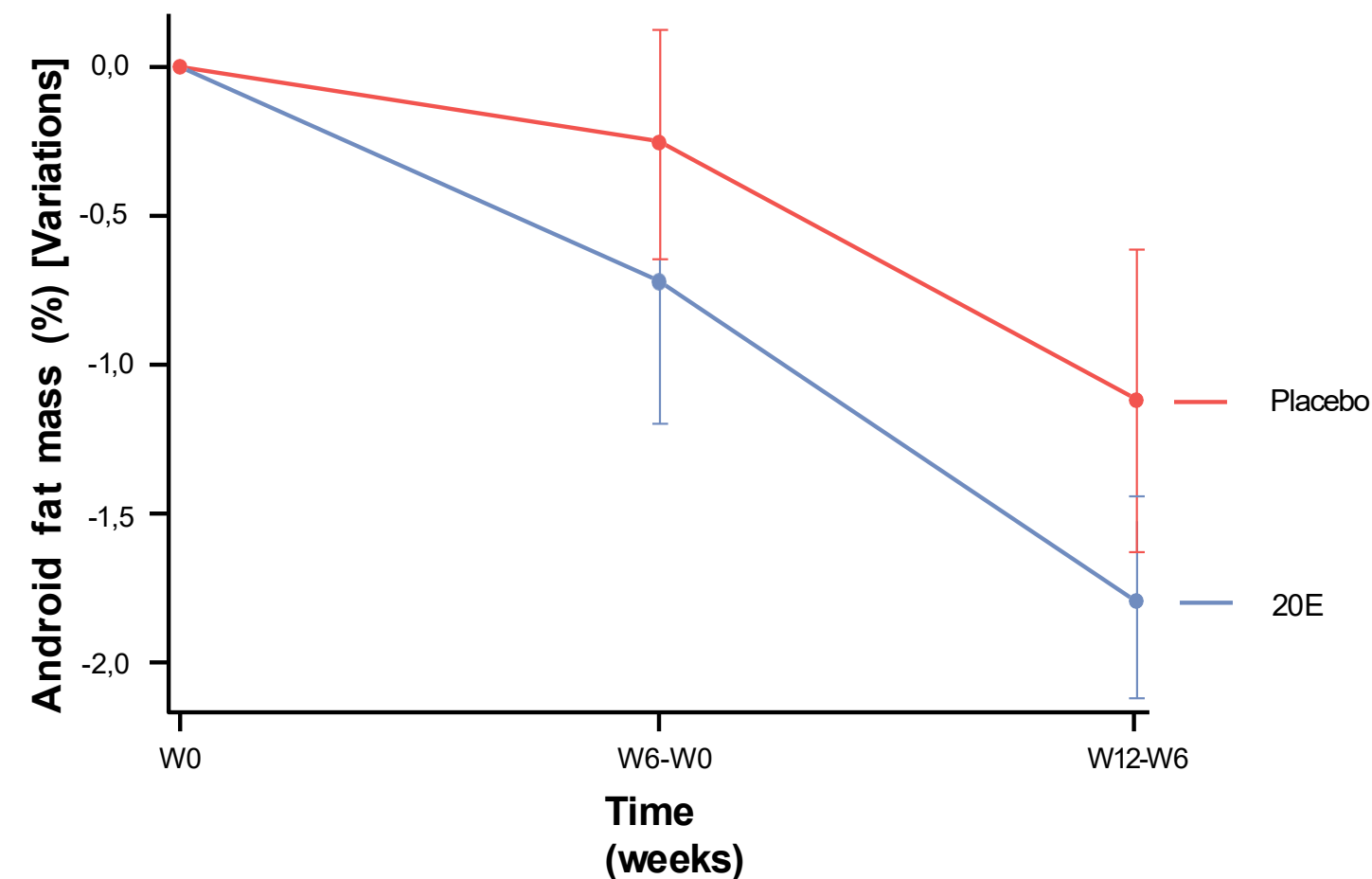


Promising clinical data in obese patients on hypocaloric diets for weight-loss



Android fat mass

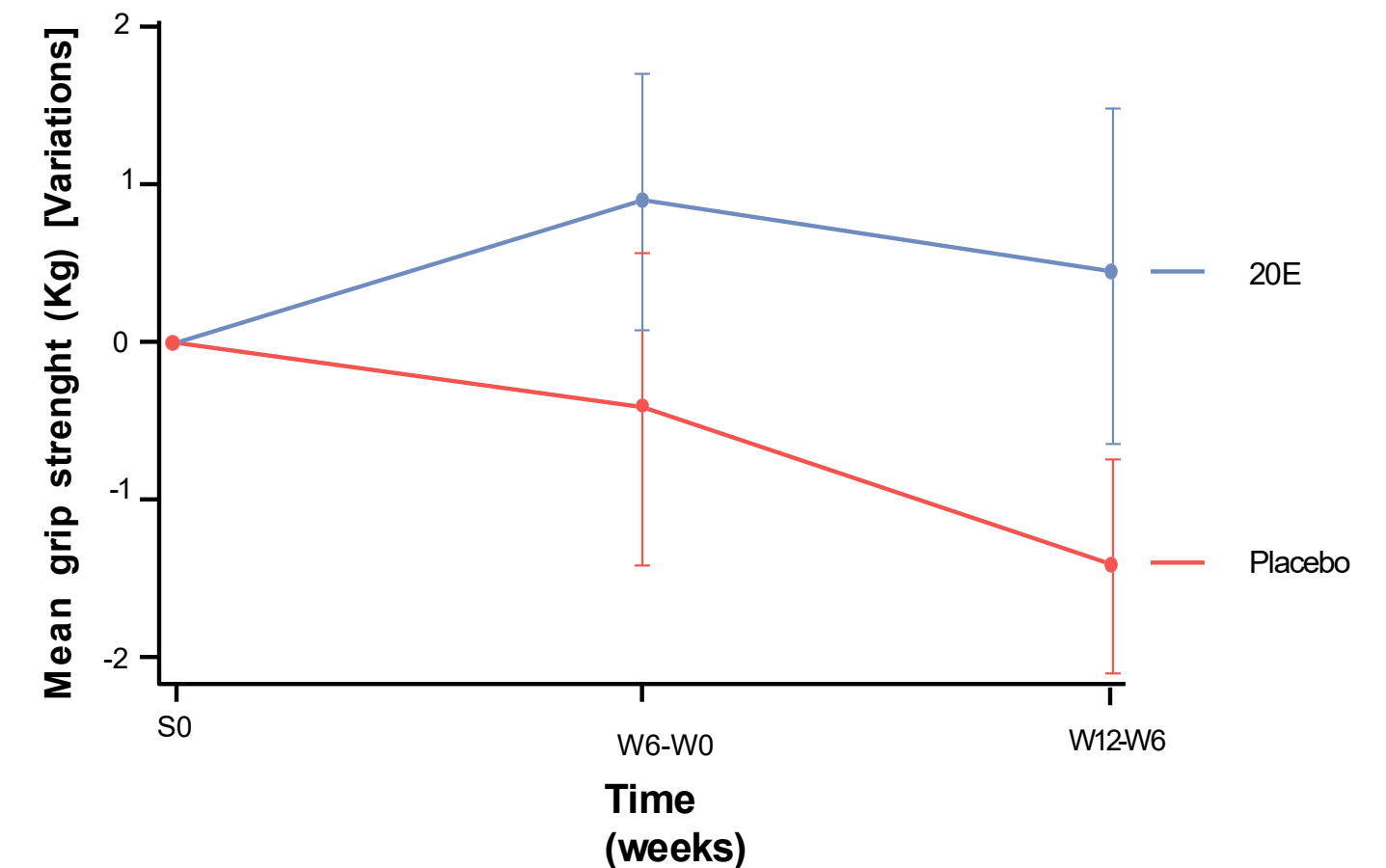
($p=0.0386$)



Handgrip strength

patients with weight loss $>5\%$

($p=0.0974$)



20-hydroxyecdysone (20E) daily dose of 37.5 mg (given orally) compared to placebo (n=58)

12 weeks study, with weight loss on hypocaloric diet for six weeks (S0-S6) followed by a normocaloric diet for six weeks (S6-S12)

Source: Foucault 2012. AgroParisTech, 2012. NNT : 2012AGPT0041. pastel-00998299





OBA – Phase 2 development plan



Studies to be conducted in the US, Brazil and Europe (Belgium). Biophytis has obtained IND approval in the U.S., filed with the EMA in Europe, and are preparing to launch the process in Brazil.

Design

- Randomized, double-blind, placebo-controlled phase 2 trial
- Assess efficacy and safety of BIO101 (20-hydroxyecdysone) 350 mg BID administered orally over 21 weeks

Endpoints

- Primary
 - Muscle strength (knee extension)
- Secondary
 - Walking speed (6-minute walking test)
 - Muscle strength normalized in relation to muscle mass
 - Weight, muscle mass and fat mass
 - Symptoms reported by patients (PROs)

Patient Population

- 164 adult obese patients treated with GLP-1 RAs, together with hypocaloric dieting
- Obese patients (BMI ≥ 30) or overweight (BMI ≥ 27 with one or more sequelae e.g. hypertension and sleep apnoea)

Product



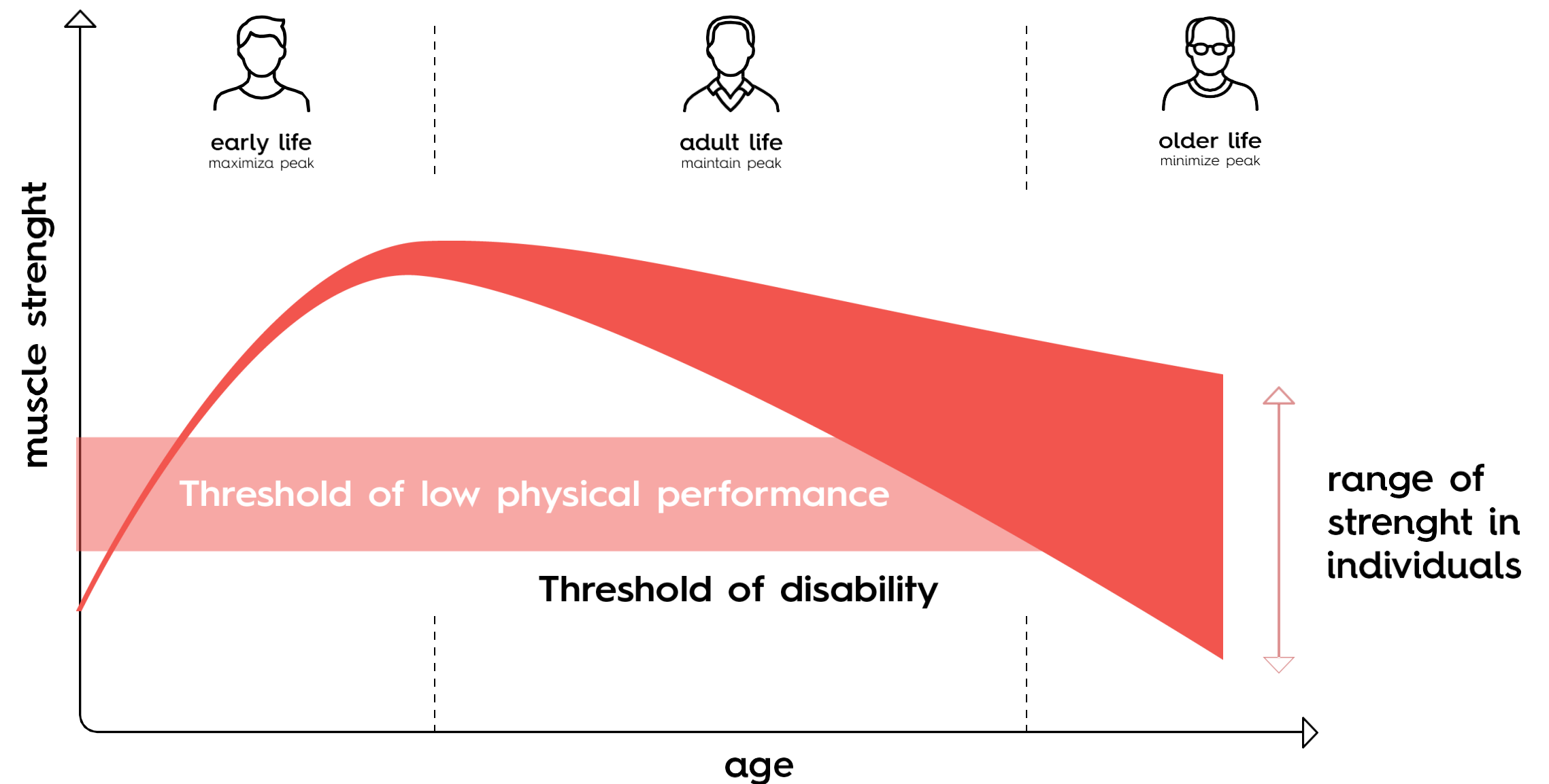
BIO101 (20-hydroxyecdysone)
in SARCOPENIA

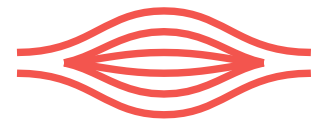




Sarcopenia is an aged related disease, with no approved drug treatments

Sarcopenia is a syndrome defined by many consortia including the EWGSOP (The European Working Group on Sarcopenia in Older People), characterized by **progressive and generalized loss of skeletal muscle mass, strength and function** associated with an increased risk of adverse events such as disability, poor quality of life and death.





Biophytis is leading the way in a huge and growing market



Up to 194 million

Patients affected by sarcopenia worldwide, **a trend that will further accelerate** in the coming years and decades with the aging of the population

265 million

Individuals aged 80 and older by the mid-2030s

No therapeutic solution exists today for treating sarcopenia

Biophytis is the most advanced company in this indication with BIO101 and the only player to have received EU and US regulatory approvals to start Phase 3 clinical study.

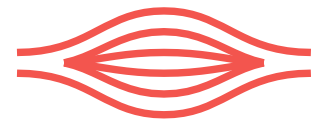


Sources:

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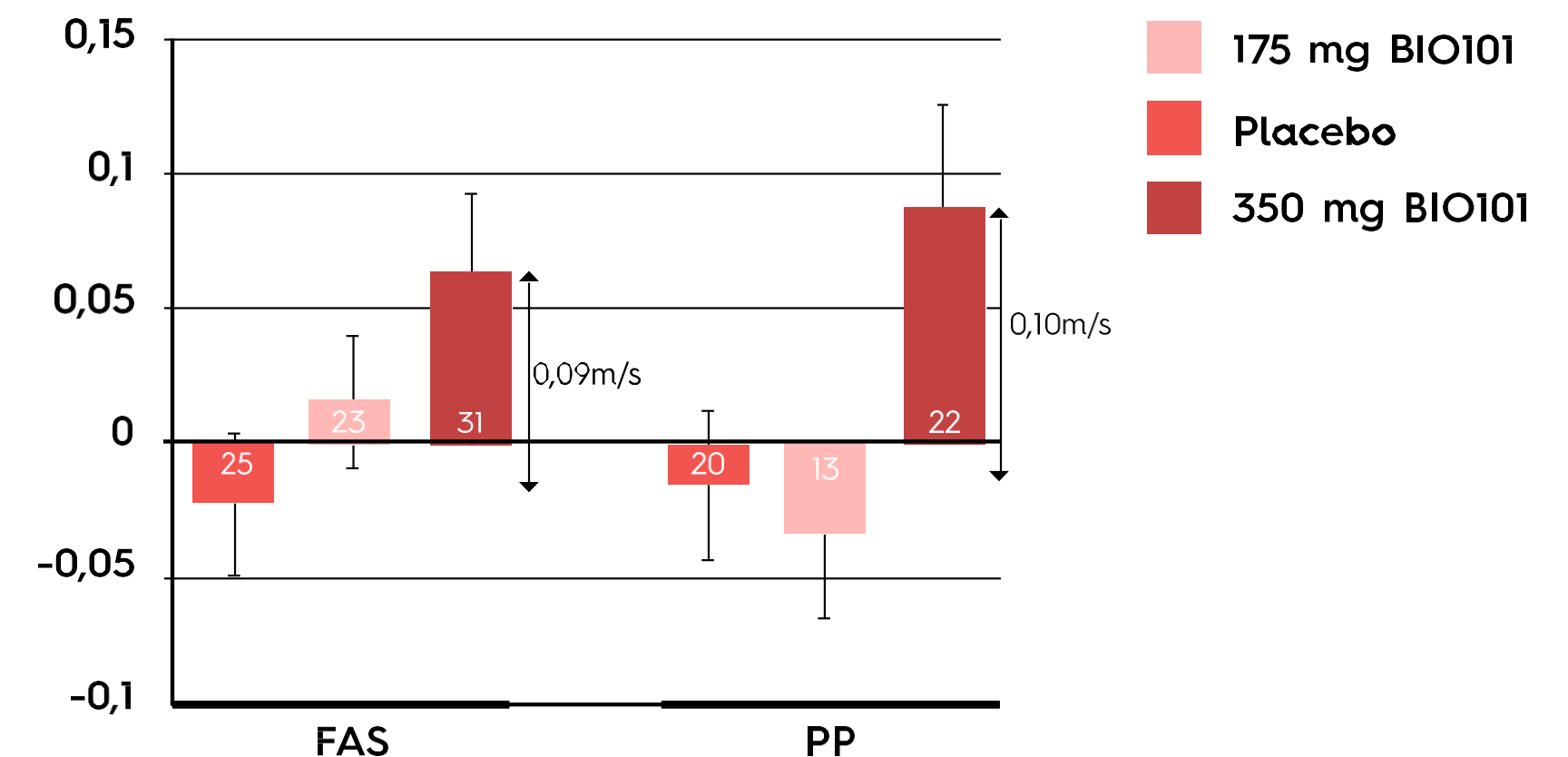
Strong results obtained in SARA-INT phase 2 trial



BIO101 (20-hydroxyecdysone) significantly improved the 400 MWT gait speed, the primary endpoint, in the PP population after 6 months of treatment

- Global, double-blind, randomized, placebo-controlled trial in patients with aged-related sarcopenia at risk of mobility disability to evaluate safety and efficacy of BIO101 (20-hydroxyecdysone)
- At the highest dose of 350 mg bid: clinically meaningful improvement of 0.10 m/s in the PP population (significant, $p=0.008$) compared to placebo for the 400MWT gait speed after 6 months of treatment
- This gait speed level of 0.10 m/s is known to be associated with a reduction in mobility disability and mortality in the elderly
- BIO101 (20-hydroxyecdysone) demonstrated the same effects on mobility in the **sarcopenic obese subpopulation**.

Change from baseline at M6 Gait speed



Treatment effect is nominally significant in PP population at M6 ($p = 0.008$)





SARA Phase 3 development plan



Biophytis to launch THE FIRST EVER Phase 3 drug clinical study in Sarcopenia

Design

- Global, double-blind, randomized, phase 3 placebo-controlled trial
- Assess safety and efficacy of BIO101 (20-hydroxyecdysone) 350 mg BID administered orally over at least 52 weeks, as compared to placebo
- Treatment effect based on estimation of the risk of mobility disability

Endpoints

- Primary
 - Major Mobility Disability (MMD) assessed by the inability to complete the 400-meter walk test (400MWT) within 15 min
- Secondary
 - Gait speed 4-meter from Short
 - Physical Performance Battery (SPPB)
 - Handgrip Strength (HGS)
 - Patient Reported Outcomes (PRO)

Patient Population

- 932 adult patients
- Age: 65 years old or over
- Low mobility measured by Short Performance Physical Battery: $3 \leq \text{SPPB} \leq 7$
- Low Handgrip Strength (HGS < 20 and < 35 kg in female and male)
- Slow walkers (gait speed < 0.8 m/s)
- Reporting a loss of motor function over the last year

Product

2023

2024

2025

2026

350 mg b.i.d of BIO101 (20-hydroxyecdysone)

CTA in Europe/US

SARA-31 Phase 3
(depending on partnership)



Scientific Advisory Board



Pr. Jean Mariani, President

Professor of neuroscience and biology of aging and Director of Charles Foix Institute of Longevity at Sorbonne University

Emeritus Professor (PU-PH) at the Sorbonne University's School of Medicine



René Lafont

Co-Founder & Professor emeritus and former Dean of the life sciences department at Sorbonne University

185 scientific articles + 59 reviews and book chapters



Dr. Roger Fielding

Professor of Medicine, Tufts University School of Medicine

Director and Sr. Scientist Jean Mayer USDA Human Nutrition Research Center on Aging



Pr. Bernard Levy

Professor Emeritus of Physiology and a senior member of PARCC

Headed the physiology department and the Inserm cardiovascular research center at Lariboisière



Pr. Jose-Alain Sahel

Chair of the department of ophthalmology at University of Pittsburgh School of Medicine and director of the UPMC eye center

Founder and director of the Vision Institute in Paris and professor at the Sorbonne's medical



Dr. Thomas Voit

Professor, University College London

Director of the Research Center of the Great Ormond Street Hospital for Children



Dr. Yann Meunier

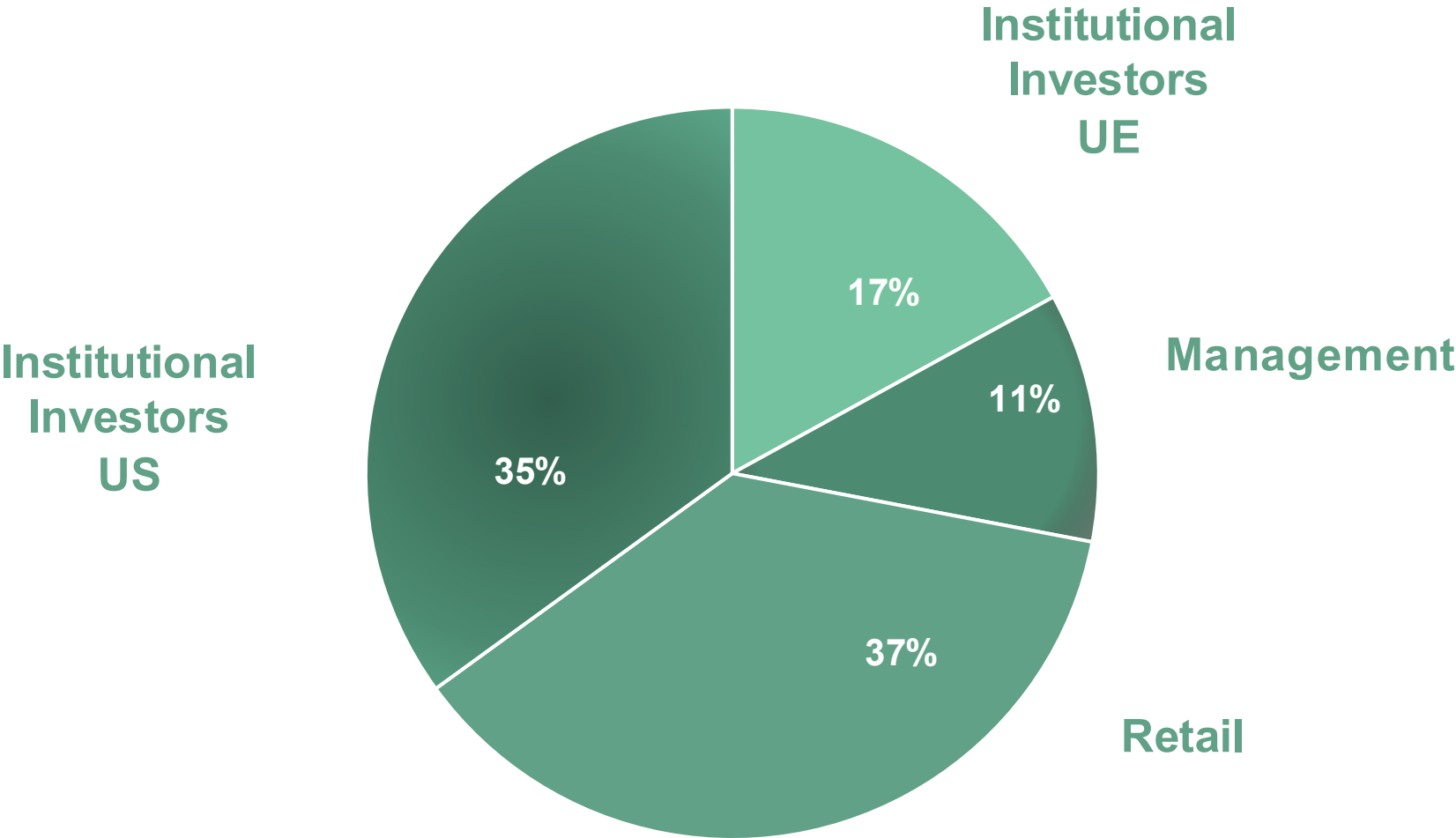
Professor, Director of the International Institute of Medicine and Science

Has led clinical trials for new treatments for HIV/AIDS

Financial data



Shareholding structure



Noteworthy Institutional Investors : *Atlas, BlackRock, Armistice*
Number of shares: **27,634,388** (July 31, 2025)



Key financial figures

Listing Euronext (ALBPS) and US market (OTC)

- Cash position: €78K (December 31st, 2024)
- Additional cash: €2.5m in January 2025 and €2.6m in March 2025 through cash contribution and private placement
- Commitment to convert €4m of financial debt (BlackRock and Atlas) at €0.30 per share, corresponding to 13.4 million shares.



Analyst Coverage

- H.C. Wainwright – Joe Pantginis, Ph.D.
- Kepler Cheuvreux – Nicolas Pauillac
- Invest Securities – Jamila El Bougrini, Ph.D.



THANK YOU

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