Collaboration between Academia and Industry:

Debiopharm International SA

Université de Genève

14 May 2019

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"Apothecaries profit is become a bye-word, denoting something uncommonly extravagant. This great apparent profit, however, is frequently no more than the reasonable wages of labour. The skill of an apothecary is a much nicer and more delicate matter than that of any artificer whatever; and the trust which is reposed in him is of much greater importance."

Adam Smith, "The Wealth of Nations", 1776

Collaboration between Academia and Industry

More than 150 years of collaboration between academia and industry in the field of pharmaceuticals.

For example:

the American Pharmaceutical Association

founded in 1852

Debiopharm: Key Features

Privately-owned:	financially independent
Headquarters:	Lausanne, Switzerland
Operational centres:	Lausanne, Martigny
Team:	staff of more than 500
International network:	over 400 experts, consultants, advisors
Key expertise:	drug development
Track record:	5 products marketed

Critical Achievements of Debiopharm

Debiopharm Group™
WE DEVELOP FOR PATIENTS

40 years

of expertise in drug development since 1979

At present

700,000

patients treated each year
with our products

2019

1,200,000

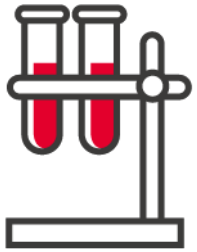
Patients
Colorectal, prostate & pancreatic cancers

Business Model of Debiopharm

1 Drug Project

Licensors:

- Academia
- Biotech
- Start-up
- Pharma



Innovation

2 Creative Drug Development

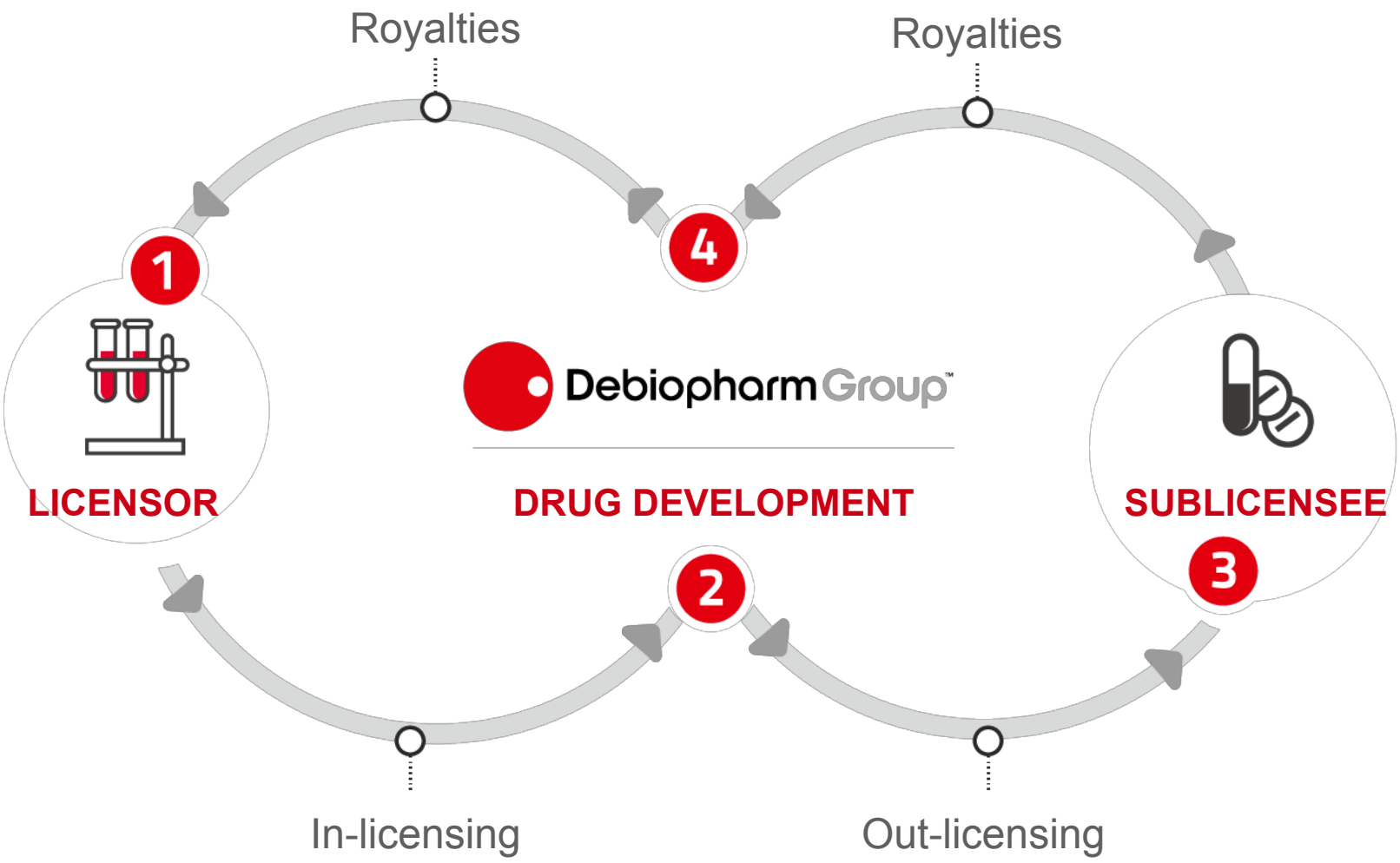
Clinical Strategy
Market Access
Project & Life Cycle Management

3 Patients

Licensees:
Mid-size &
Major Pharmaceutical Companies

Commercialization

Contractual Relationships



Contractual Relationships with Universities

- Confidentiality agreements (CDA)
- Consulting agreements
  (with a professor or with a University)

- Material transfer agreements
- Service agreements
- Research and development agreements

- «Endowment» agreements
- Awards
  (Japanese Cancer Association:
  JCA Mauvernay Award)
- Financing of a chair

- Master service agreements
- Master research agreements

- Investment in the share capital of a start-up (spin-off from Universities)

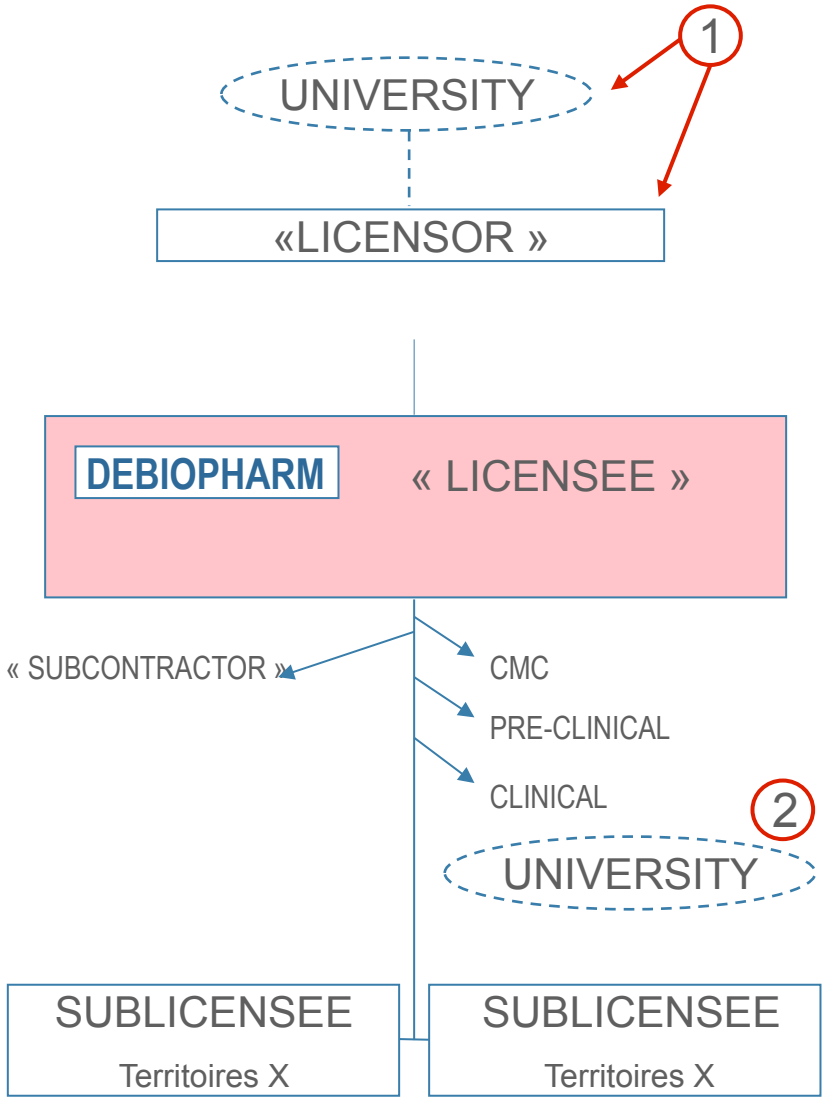
- Licensing agreements (in-licensing)

Business Model of Debiopharm

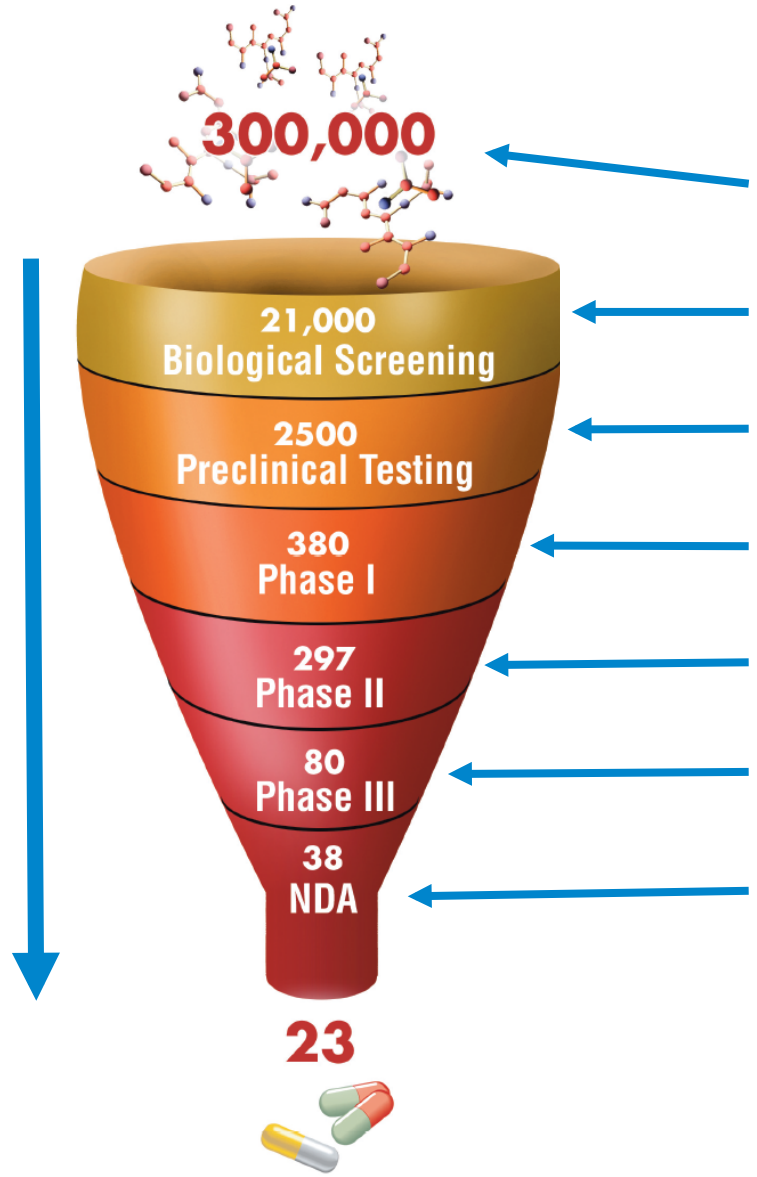
License agreement (in-licensing) regarding a compound: framework for all the other conditions in the development program:

- Confidentiality
- Publications
- Intellectual Property: ownership/ licensed rights
- Insurance
- Warranties
- Termination

Out-licensing agreement: essential conditions pertaining to the commercialization of products by licensees



Development is Very Risky!



Success Rate

0.008% of patents

0.1% of pre-clinical screenings

0.9% after pre-clinical evaluations

6% of phase I clinical trials

8% of phase II clinical trials

29% of phase III clinical trials

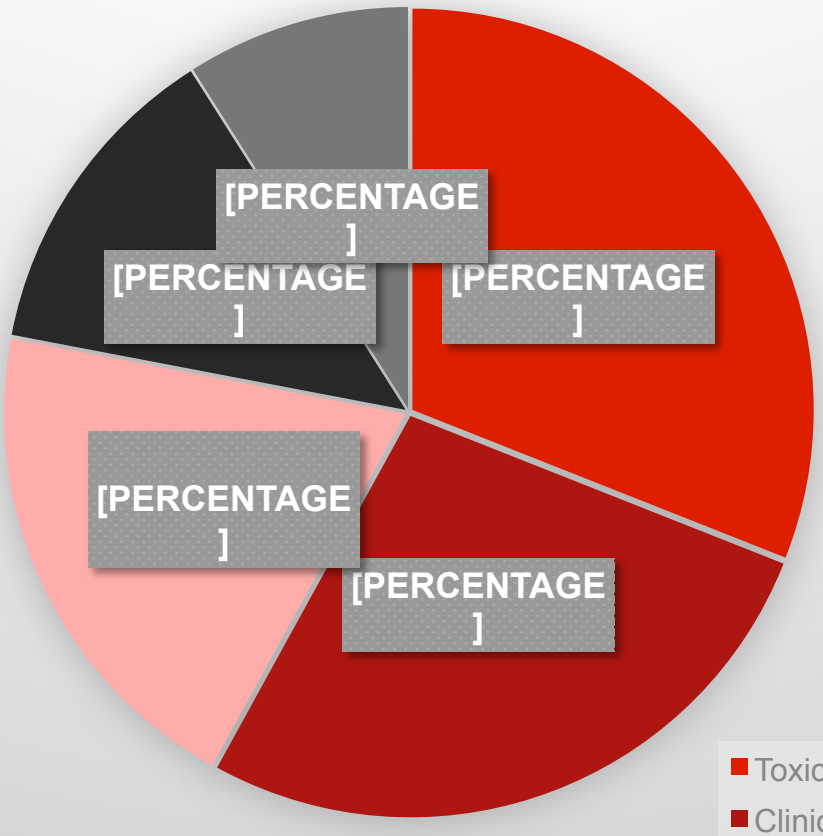
61% of marketing authorizations

Development Risks

Development stage:	Success rate:	Probability of bringing a product to market:
Pre-clinical	50%	10%
Phase I	70%	20%
Phase II	50%	30%
Phase III	70%	65%
FDA Filing	90%	90%

Based on figures published in “Die Pharmaindustrie”, Dagmar Fischer and Jörg Breitenbach, third edition, 2010

Reasons for Terminating a Program



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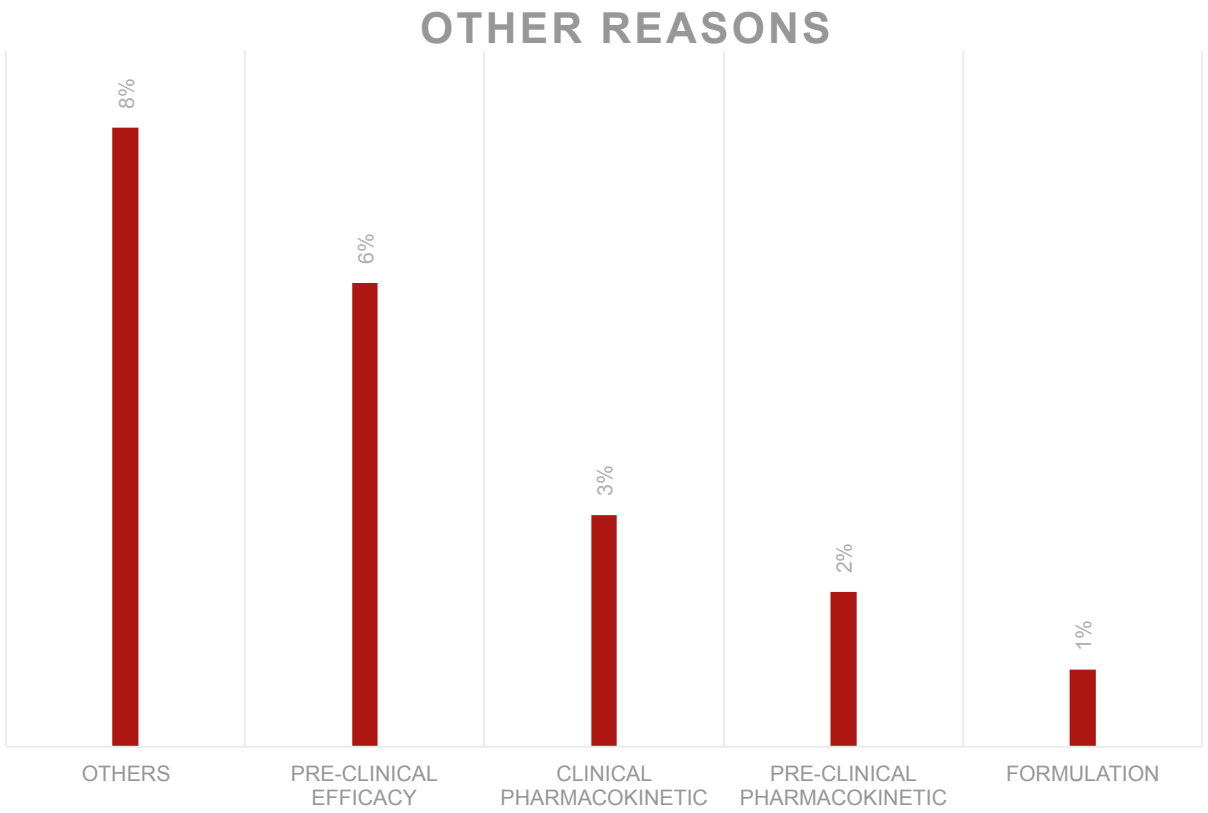
Reasons for Terminating a Program



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Entry to Market

Entry to market:	Market share:
First company	28%
Second company	22%
	50%
Third company	18%
Fourth company	12%
Fifth company	5%

Based on figures published in “Die Pharmaindustrie”, Dagmar Fischer and Jörg Breitenbach, third edition, 2010

Intellectual Property - Goals and Challenges

Secure the **exploitation of commercial** drug candidate (DC) (FTO)

Specifically protect the DC

Preserve a **longer exclusivity period** (after data exclusivity)

Obtain a **strong patent,** at least for the DC

Obtain a broader claim

Facilitate and accelerate patent application examination in key markets

Preserve **life-cycle management**: obtaining additionnal patents

Likelihood of a **competitor's earlier filing**

Patent not granted: lack of inventive step/insufficient description

Patent invalidated: insufficient written description/lack of inventive step

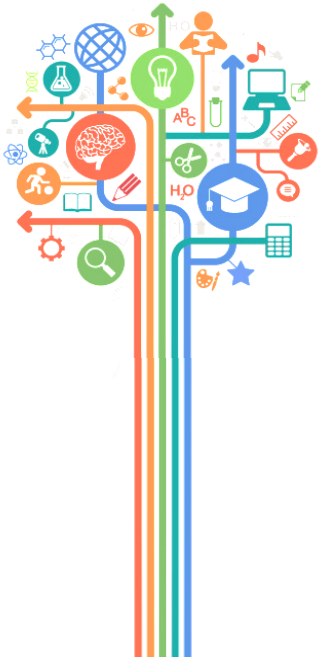
Secure Likelihood of **non-authorized disclosure**

R&D work to be conducted by academics

Purposes for Collaboration with Academia

1. **In-Licensing Projects / Acquisitions**:
   - New Chemical Entity and New Biological Entity
   - In oncology: all types, no vaccines, focus on targeted therapies
   - In infectious diseases: targeted antibiotics, gram negative antibiotics

2. **High Level of Expertise / Competences to**:
   - Develop cost effective drug / a diagnostic arm
   - Redesign molecules
   - Enhance patient access in emerging economies
   - Explore new technologies, generate valuable knowledge
   - Find solutions to solve a specific existing problem



Collaborations with Academia: Expectations

What do we look for when reaching out to a Professor for a collaboration?

- Their expertise and valuable opinion in the field of interest
- Well-known Key Opinion Leaders (KOLs) allow to improve the credibility of our project and to capitalize on their network
- Presence in their laboratory of a specific technique, animal model, or access to relevant clinical samples

Local contacts are privileged as communication is easier and frequent.

Face to face meetings are possible, however this is not an absolute requirement.

How to Identify Academics / How to Proceed

How do we find who we could collaborate with ?

- Personal networks within our organization
- From the literature/conferences/university websites/consortiums
- Scouting team when looking for new opportunities
- Influencer Map: visual representation of the landscape of influencers of relevance to a project and how they are connected

How to proceed, 2 step- process:

- Non-confidential information to be exchanged (package for In-licensing)
- Signature of a confidentiality agreement (CDA; bilateral) to exchange confidential information

Expectations for In-licensing Project

Information Package (not a 1 page document)

Tell a story, talk about the future market, don't talk about the history of the research

- Short power point presentation with non-confidential data
  (a patent application is not enough)
- Sell your product:
  - Indication, medical need
  - Type of molecule
  - Relevance of target, describe MOA
  - Stage of development:
    - *Efficacy data*
    - *Safety data*
- Important to highlight therapeutic areas and development stage:
  (we want to see in vivo efficacy data) and the unique properties of your project
- Disclose potential issues, we will find out eventually anyways

Provide as much data as possible!

Practical Issues when Negotiating an Agreement

1. Preparation: who shall sign?
    - Under their name or the name of the University?
    - Who is authorized to sign?

2. Who shall Approve?

Practical Issues: Invoices

3. Invoice / costs:

- Invoices to be sent regularly

  (Do not send invoices regarding incurred costs two years later.)

- Transparency regarding costs

Practical Issues: MAJOR CONCERNS - GOALS

Misalignment between us and the professor/university in terms of goals or needs:

- Timing of publications, often too early (even caused one project to be stopped).

"Professor was looking for visibility and therefore wanted to do a large clinical study, we wanted a quick proof-of-concept and were only willing to do a smaller and simpler study"

Practical Issues: GOVERNANCE

Lack of communication and governance problems

> "Professor was managing the research in his laboratory as if he was the owner of the project. We were not empowered, and the decisions we made were not followed"

Practical Issues: DIFFICULTY TO COLLABORATE

Unwillingness to collaborate and share the knowledge

"As a condition for a collaboration with his laboratory, a professor required a consultancy agreement. This agreement had to be done on his own terms: a monthly payment fee without notion of number of hours of services, and no requirement of written reports"

"The same professor, when solicited for consultancy, was systematically unwilling to commit and share his knowledge: we paid him for nearly 1½ years for almost nothing in exchange"

Conclusion: Collaboration YES, IF ….

Implement collaborations where:

- Exclusivity on our Project: preserved/enhanced

Monitoring the risks:

- Free exchange of ideas /timely dissemination of results

Alignment on goals/needs: is key

- Need to clearly define goals and responsibilities

Agreements negotiated on a case by case basis

- But academics need to be prepared

Time is of the essence!

Thank you for your attention

Debiopharm Group™
WE DEVELOP FOR PATIENTS

Do you have any questions ?

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