

Deloitte Recap Executive Analysis



Licensor Amylin

Product

Pramlintide/metreleptin, davalintide, OPT, and other compounds from both parties' research programs including Takeda Y-family agonists

Licensee Takeda

Field

Diabetes and Obesity

Date: 10/09

Territory: WW

Pre-Commercial Paymts & Rights

Upfront Payment

- \$75M

R&D Costs

- Takeda pays 80% of US costs
- Takeda pays 100% of ex-US costs
- Joint committee may overrule cost-sharing of any budget overruns
- Amylin responsible for trials through Phase II for U.S. approval
- Takeda conducts all other studies

Unanticipated Cardiovascular Study:

- If CV Safety study becomes required for approval by FDA, Takeda will pay CON% and Amylin will pay CON% of costs
- Takeda loan to cover costs above CON cap

Milestone Payments

Takeda pays Amylin (total >\$1B):

- 7 dev/reg payments for each product
- 3 sales mstones for BID and QID products
- 3 sales mstones for QW products
- 5 other sales milestones

\$200M dev mstones for 2 products

\$50M dev mstones for addtl products

\$140M product launch paymts per product

\$800M sales milestones per product

Milestones discounted to the degree product contains Takeda compounds

Termination Rights

Either party may terminate for:

- breach or bankruptcy of the other party
- patent challenge to other party's patents
- Safety threat
- Lack of commercial viability
- Blocking 3rd party IP

Reversion Rights upon Termination

Rights to Amylin on Takeda breach, patent challenge, mutual or Takeda-only term. for safety, blocking 3rd party IP, commercial viability:

- CON% royalty to Takeda for trademark
- CON% royalties to Takeda if product contains Takeda compound

Rights to Takeda on Amylin breach, patent challenge, or Amylin-only term. for safety:

- CON% royalty to Amylin

Commercial Payments & Rights

License Grant

Amylin grants Takeda exclusive license to make use and sell Licensed Products

Excluded Products & Fields:

- Metreleptin alone
- Pramlintide alone (Symlin) or in combination with other compounds not licensed herein
- Psychiatric field (licensed to Psylin)

Booking of Sales & Commercial Rights

- Takeda books sales and responsibly for all commercialization
- Takeda may request Amylin's assistance in commercial activities (non co-pro activities), to be reimbursed at Takeda FTE rate

Sublicense Rights

- Takeda may sublicense
- Amylin's consent required for U.S. rights

Royalty or Profit Split

4 tiers for each of Tier 1-3 Products:

- Tier 1 Products: Amylin cmpd other than OPT
- Tier 2 Products: Amylin compound and OPT or Takeda compound or Amylin option cmpd
- Tier 3 Products: anything else

Term of Agreement

- Initial Royalty Term ends on expiration of regulatory exclusivity, patent life, or entry of generics
- Secondary Royalty Term ends on earlier of CON years after Initial Term or when generic unit sales exceed brand unit sales
- CON% royalty due during Secondary Term

3rd Party IP

- Amylin makes all Davalintide-related payments under the Amylin In-License Agmts (Amgen, Curis, Pacira, Univ of Minnesota)
- Parties share Con%/Con% payments under elective 3rd party licenses
- Parties share costs under mandatory 3rd party licenses

Change of Control

On change of control of either party, other party has unilateral decision rights for all steering committee decisions

Manufacturing Rights

- To be negotiated
- Cost of supply from one party to another at COGS wo. Markup
- Amylin to supply clinical matl
- Takeda right to select formulation and packaging for Phase III trials

Amylin U.S. Co-Promotion Rights

- Amylin option to co-promote first 2 products w. different active ingredients and addtl products w. same ingredients
- Amylin may exercised win CON of Ph3 unblinding of U.S. study
- Amylin details up to CON%, determined by Takeda
- Takeda to reimburse Amylin details at CON% of Takeda's PDE cost
- Takeda provides initial training
- initial co-pro term of CON

Governance & Disputes

- Takeda has sole decision-making authority for ex-US development
- Takeda sole decision-making authority over commercial decisions
- Any other matters, including U.S. development costs may be submitted to arbitration if Executives cannot agree

Standstill

- Takeda 3-year standstill
- Canceled if 3rd party acquires more than 15% of Amylin or Amylin announces intent to combine
- Most favored licensee terms apply

New Development & Opt-In

- Each party to nominate addtl compounds from its libraries that meet certain criteria
- New Compounds and Development Projects submitted to OSC
- Either party may proceed independently if OSC does not approve
- Other party may Opt In at Phase II or Phase III
- Opting in party pays CON% at Phase II or CON% at Phase III of other party's incurred development costs

See back page for Accounting Appendix, if applicable