

Dealdoc**Development and licensing agreement for Enbrel biosimilar**

Merck and Co
Hanwha Chemical

Jun 13 2011

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Companies:	Merck and Co Hanwha Chemical
Announcement date:	Jun 13 2011
Deal value, US\$m:	720.0 : sum of upfront and milestone payments

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Details

Announcement date:	Jun 13 2011
Industry sectors:	Bigpharma Generic pharma Pharmaceutical
Therapy areas:	Dermatology » Psoriasis Musculoskeletal » Arthritis » Psoriatic arthritis Musculoskeletal » Arthritis » Rheumatoid arthritis
Technology types:	Biological compounds Biosimilars/Bio-betters Bigpharma outlicensing
Deal components:	Development Licensing Technology transfer
Stages of development:	Formulation
Geographic focus:	Worldwide
Excluded geography:	Asia » South Korea Europe » Turkey

Financials

Deal value, US\$m:	720.0 : sum of upfront and milestone payments
Upfront, US\$m:	n/d : upfront payment
Milestones, US\$m:	n/d : additional payments associated with milestones for technology transfer and regulatory progress
Royalty rates, %:	n/d : tiered royalties on sales

Termsheet

Key Deal Terms Summary

1. Agreement Overview

- **Hanwha Chemical Corporation** (through its Bio Business Unit) and **Merck & Co.** (through Merck Sharp & Dohme Research Ltd.) entered into an **exclusive global license and collaboration agreement** to develop and commercialize **HD203**, Hanwha's biosimilar candidate to **Enbrel® (etanercept)**.

Territorial Rights:

Merck: clinical development, manufacturing, and global commercialization rights.

- **Hanwha:** retains rights in **South Korea and Turkey**.
- The agreement is set to last until **end of 2024**.

2. Financial Terms

- Deal value estimated at **USD 720 million**.

Structure:

Upfront payment from Merck to Hanwha.

- **Milestone payments** tied to technology transfer and regulatory progress.
- **Tiered royalties** on global sales (excluding Korea and Turkey).
- Specific payment breakdown was not disclosed in official releases.

3. Development & Commercialization Plans

- **Merck:** responsible for **clinical development** and **manufacturing** of HD203, and global commercialization post-approval.
- **Hanwha:** continues development activities in Korea, where **HD203 is in Phase III trials** in rheumatoid arthritis patients (evaluating equivalence to Enbrel in combination with methotrexate).
- Clinical trials in the **U.S.** and other major markets were planned but not yet initiated at the time of announcement.
- The collaboration integrates Hanwha's biosimilar expertise with Merck's global commercial infrastructure and biologics portfolio (via **Merck BioVentures**).

4. Strategic Impact

- Provides **Hanwha** with its first **major international biopharma partnership**, validating its biosimilar R&D strategy.
- Strengthens **Merck's biosimilars portfolio**, with Enbrel regarded as one of the **most important biologic targets** for biosimilar competition.
- Enhances global patient access to **lower-cost biologic therapies** for autoimmune diseases such as **rheumatoid arthritis** and other inflammatory conditions.
- Marks a significant step in South Korea's emergence as a player in the **biosimilars market**.

Overall Summary

Hanwha Chemical signed a **USD 720 million global biosimilar licensing deal** with **Merck** for **HD203 (etanercept biosimilar)**. Merck will oversee **clinical development, manufacturing, and global commercialization** (ex-Korea/Turkey), while Hanwha retains rights in its home market and Turkey. The agreement includes **upfront, milestone, and royalty payments**, and runs through **2024**. The partnership provides Hanwha with critical global reach and validates its biopharma ambitions, while Merck strengthens its biosimilars portfolio with a high-value candidate in autoimmune disease.

Press Release

13 June 2011

Hanwha wins \$720 million biosimilar license deal with Merck

South Korea's Hanwha Chemical said on Monday it had won a license deal worth \$720 million for its biosimilar product with Merck Sharp & Dohme Research Ltd, a subsidiary of U.S. drug firm Merck & Co.

The contract will cover global sales of the licensed product excluding South Korea and Turkey and will last until the end of 2024, Hanwha said in a statement.

13 June 2011

Merck and Hanwha Chemical Corporation Establish Global Strategic Collaboration to Develop and Commercialize Biosimilar Candidate
Collaboration to develop and commercialize candidate biosimilar form of Enbrel®

WHITEHOUSE STATION, N.J. & SEOUL, South Korea--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, and Hanwha Chemical Corporation (KOSPI: 09830) today announced that they have entered into an exclusive global agreement to develop and commercialize a candidate biosimilar form of Enbrel® (etanercept).

Under the terms of the agreement, Hanwha Chemical Corporation, through its Bio Business Unit, and Merck, through a subsidiary, will work together to develop and commercialize HD203, a candidate biosimilar form of etanercept developed by Hanwha. Merck will conduct clinical development and be responsible for manufacturing. In addition, upon marketing approval, Merck will commercialize HD203 globally, except for in Korea and Turkey where Hanwha has retained marketing rights. In return, Hanwha receives an upfront payment from Merck and will be eligible for additional payments associated with milestones for technology transfer and regulatory progress as well as tiered royalties on sales. Specific financial terms of the agreement were not disclosed.

"This collaboration to develop and commercialize our lead biosimilar candidate with a leading global health care company such as Merck represents a significant event both strategically and financially for Hanwha and underscores the success of our biopharmaceutical strategy," said K.J. Hong, chief executive officer Hanwha Chemical Corporation. "We are excited and proud that Hanwha's biobusiness is now well positioned to make a major contribution toward providing access to a biosimilar form of one of the world's leading biologic therapies."

"Hanwha has established outstanding biopharmaceutical development capabilities," said Michael Kamarck, president, Merck BioVentures. "Enbrel is widely considered to be one of the most important biosimilar molecules. This candidate represents a valuable addition to our broad biosimilars portfolio, as we advance our strategy to provide patients with improved access to biologic therapies."

HD203 is currently being evaluated, in Korea, in a randomized double-blind active-controlled parallel group Phase III clinical trial to evaluate the equivalence in efficacy and safety of HD203 and Enbrel in combination with methotrexate in patients with rheumatoid arthritis. Clinical trials have yet to be initiated in the United States.

About Hanwha Chemical Corporation

Hanwha Chemical Corporation has been a pioneer since its establishment in 1965. Hanwha Chemical Corporation has led the development of Korean petrochemical industry by producing basic products, i.e. PVC, LDPE, LLDPE, CA, often compared as "the staple" of industries. Today, Hanwha Chemical Corporation is focused on strengthening core competencies by developing specialty and eco-friendly products and exploring overseas markets, while identifying new growth engines, such as renewable energy resources, biopharmaceuticals, and nano materials. For more focused investment and efficient Bio-business activities, Hanwha Chemical Corporation established a Bio Business Unit focusing on R&D of biopharmaceutical product. For more information, visit www.hanwha.co.kr.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com.

Filing Data

Not available.

Contract

Not available.