Henlius

HLX02 (Trastuzumab) EU GMP Status Update

April, 2020

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Mission & Vision

Mission

"To improve patients' lives by timely providing them with **quality** and **affordable** protein therapeutics through technical **innovation** and operation **excellence**."

Vision

"Be the most **trusted** and **admired** biotech company providing innovative and affordable medicines to **all patients**."

- Reliable Quality
- Affordable Innovation
- Biosimilars + Bio-innovatives + Combo
- Leading Technology Global Footprint

‘Trastuzumab)
EU GMP Approval

1.1 Henlius HLX02 (Trastuzumab) of Xuhui Facility Received Official EU GMP Approval

GMP Certificate

- Certified product：HLX02 (trastuzumab for injection) (lyophilized powder)
- [illegible] Chief Pharmaceutical Inspector (a health regulatory body in Poland)
- Certification scope：[illegible] management, lyophilized drug product line in Xuhui facility
- Valid period: 3 years

Applicable Regions

- According to the GMP mutual recognition system of EU member states, the Company's Xuhui Facility has met the GMP standards of the EU
- EU GMP certification can be mutually recognized and shared among nearly 30 member states
- Inspection results can be shared with nations such as U.S. and Canada which signed Mutual Recognition Agreement (MRA)

Global Impact

- "EU Guidelines for Biosimilars" (CHMP/47/04) took effect in 2005, [illegible]'s first guiding principle for biosimilar research and evaluation
- EU GMP certification is one of the world's most authoritative and stringent certifications, it has a significant global influence and is [illegible]

Xuhui Facility

1.2 EMA application for HLX02 (Trastuzumab) Accepted in June, 2019

HLX02 Registration Application Process

1.3 Henlius Established Strict Quality System Based on Global Standards since Inception

1.4

Inspection Org	Fosun Pharma Expert	Fosun Group	Business Partners	NMPA	SFDA	Foreign Drug Regulatory Agencies
Inspection #	**30**	**9**	**3**	**4**	**20**	**1**
Inspection Reason	Continuous improvement of quality system	Routine Inspection	DD/Quality audit	NDA Inspection	- Acceptance Inspection - GMP Certification - Manufacturing Permission	EMA Marketing Authorization Application
Inspection Scope	All Quality Systems	All Quality Systems	All Quality Systems	All Quality Systems	All Quality Systems	All Quality Systems

- Conducted multiple inspections / audits with the help of domestic and foreign regulators
- Invited domestic and foreign experts for mock audit / consultation, (e.g. UK, Poland, US)
- Completed more than 1,600 quality system improvements

1.5 A Significant Value for Facilities with EMA/FDA GMP Certification [illegible]

	Acquirer	Owner of Manufacturing Facility	Facility Information	Approximate Time	Deal Value (USD)
1	FUJIFILM Value from Innovation	Biogen	■ [illegible] Denmark ■ **Capacity:** - 6 X 15,000L Bioreactors ■ **Certification:** EMA	2019	~$890M
2	Catalent CONSUMER HEALTH	COOK PHARMICA	■ **Deal Location:** USA ■ **Capacity:** - [illegible] - [illegible] - [illegible] 100L Bioreactors ■ **Certification:** FDA	2017	~$950M
3	AGC	CMC biologics	■ **Deal Location:** USA/Denmark ■ **Capacity:** - 1 X 2,000L Bioreactor - 2 X 1,500L Bioreactors - 5 X 3,000L Bioreactors ■ **Certification:** FDA/EMA	2016	~$510M

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Globalization Strategy

2.1 Advance with High Quality Standard – Implementation of Globalization Strategy of HLX02 (Trastuzumab)

2.2 Our Partner Accord Will Commercialize HLX02 for EU While Henlius Will Be Responsible for China Market

Henlius/Accord Transaction Regarding HLX02

- Henlius grants Accord exclusive license to commercialize HLX02 in Territory (53 countries in Europe, 17 in Middle-East North Africa, and some CIS countries) including but not limited to sales, import, distribution, and other commercialization activities
- Henlius will receive milestone payments (not exceeding USD 40.5 million) and royalties
- Through its global R&D, manufactory and sales network, Accord will accelerate the expansion of overseas market

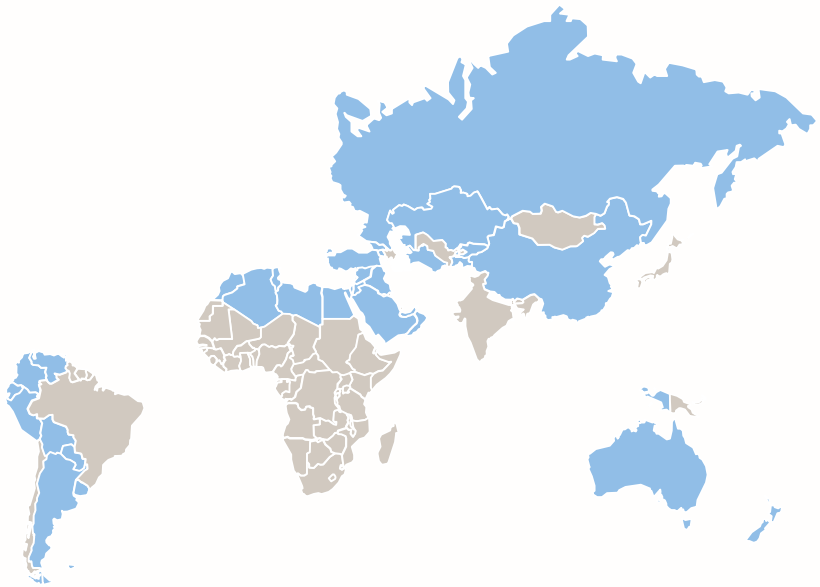
About Accord

- Accord is a **global** pharmaceutical company primarily engaged in the business of developing, manufacturing and marketing generic products and biosimilars in North America, Europe, Australia, South Africa, and other regions
- Ranked **top three** in Europe for sales of generics, and **No.1** for sales of generics in **oncology**
- **+ 8,500 generic products** on market, covering more than 85 countries with a strong portfolio of products in areas including cancer, heart, disease, mental illness, and diabetes
- Products manufactured under International Standards in plants approved by USFDA, MHRA, EMA, TGA, MCC, ANVISA, etc
- Committed to providing high quality and affordable products and services to patients, with the goal of becoming the world's leading healthcare provider

Key terms

Licensor	Shanghai Henlius Biotech Inc.
Licensee	Accord Healthcare Limited
Effective Date	2018-06
Product	HLX02 (Trastuzumab)
Territory	Europe, Middle-East North Africa, Commonwealth of Independent States ("CIS")
License granted to Accord	Exclusive rights for the commercialization of the Product and exclusive supply
Milestone Payments	▪ Upfront on the effective date: **USD 8 million** ▪ Upon EMA's acceptance of the MAA submission: **USD 5 million** ▪ On Day 105 of the centralized procedure: **USD 5 million** ▪ Upon EMA's approval of the MAA: **USD 5 million**
Royalties	**13.5%-25% of the net sales**

2.3 EU GMP Approval Is a Major Milestone and First Step for Us to Establish Strong Global Commercialization with Our Strategic Partners



Note：as of March 31, 2020

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Review and Outlook

3.1 Henlius [illegible]

[illegible] focus of 2020, will become an engine and a cornerstone of Henlius commercialization

Enhance manufacturing capacity:

- Accelerate capacity [illegible] and **maximization**, as well as build brand image of "[illegible]"
- Strategic planning of long-term domestic and overseas biopharmaceutical manufacturing base

Innovation of commercialization model:

Win-Win strategy of multiple-party cooperation: actively collaborate with multiple partners such as PhIRDA, building a domestic biosimilar ecosystem together, demonstrating "the most reliable" value

[illegible] operation:

Sales team management

Market penetration

Access (pricing strategy, payment plan etc)

Business development:

Organization model based on talent + ability + culture:

- Best talent
- Highly efficient team
- Strong focus on Compliance

3.2 Recent Progress Strengthens Our Confidence to Achieve Full Year Target

	Major Milestones	Current Status	Guidance
Products /Development	▪ HLX02 EMA MAA approval ▪ HLX02 China NDA approval ▪ Other products	▪ GCP、GMP approved ▪ On progress as scheduled ▪ On progress as scheduled	▪ HLX02 approved in EU in 2H20 ▪ HLX02 China approval and launch in mid-2020
Manu-facturing	▪ HLX01 2,000L sNDA approved ▪ Songjiang Plant One pilot production	▪ Approved on April 14, 2020 (see previous announcement) ▪ Pilot production started in early April 2020	▪ End of April/ early May ▪ 2Q20
Others	▪ STAR board (A share) listing	▪ Kick-off 2020 (on March 3(see previous announcement)	

Reliable Quality | **Affordable** Innovation