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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
- Quality Focus · Global Footprints

HLX02 (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)
- Certification body：Chief Pharmaceutical Inspector (a health regulatory body in Poland)
- Certification scope：drug substance, cell bank preparation, storage and management, lyophilized drug product line in Xuhui facility
- Valid period: 3 years

Applicable Regions

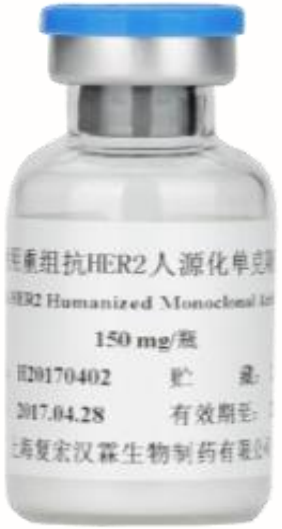
- According to the GMP mutual recognition system of EU member states, the Company’s Xuhui Facility has met the GMP standards of the EU
- EU GMP certification can be mutually recognized and shared among nearly 30 member states
- Inspection results can be shared with nations such as U.S. and Canada which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

Global Impact

- “EU Guidelines for Biosimilars” (CHMP/47/04) took effect in 2005, which is the world’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 considered as a “PASS” for drugs to access global markets

Xuhui Facility

1.2 EU MAA Application for HLX02（Trastuzumab）Accepted in June, 2019



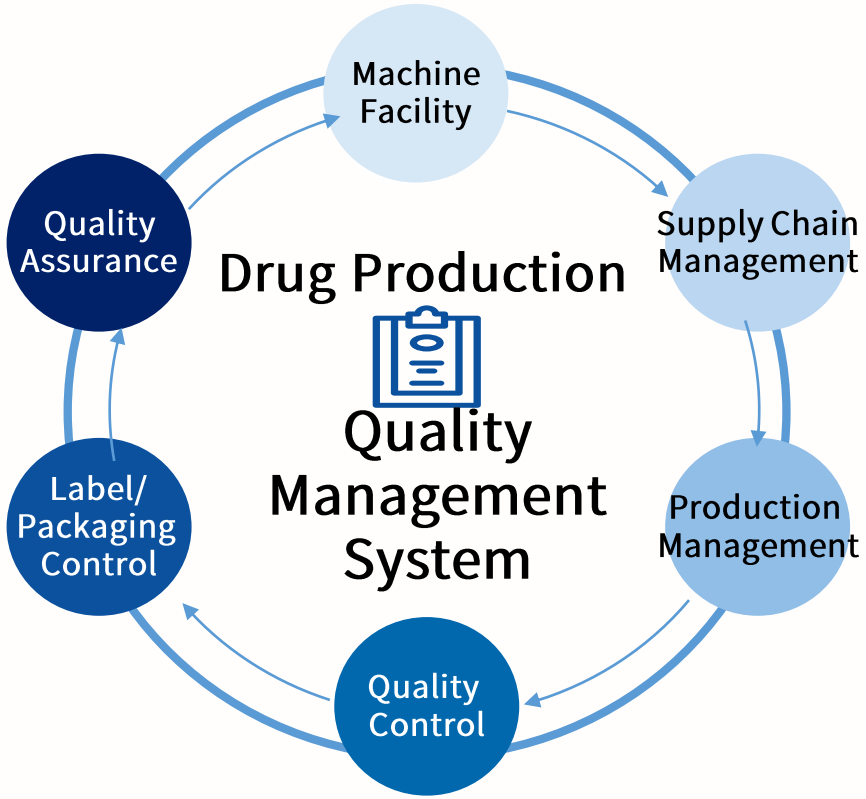
Generic Name	Trastuzumab
Originator Drug	Herceptin® (Genentech & Roche) USA：Approved in 1998 EU：Approved in 2000 China：Approved in 2002
HLX02	Recombinant Anti-HER2 Humanized Monoclonal Antibody Powder for Concentrate for Infusion Biological Product for Treatment International Multicenter phase III clinical Trials
Indications	Metastatic breast cancer, early-stage breast cancer, metastatic gastric cancer

HLX02 Registration Application Process

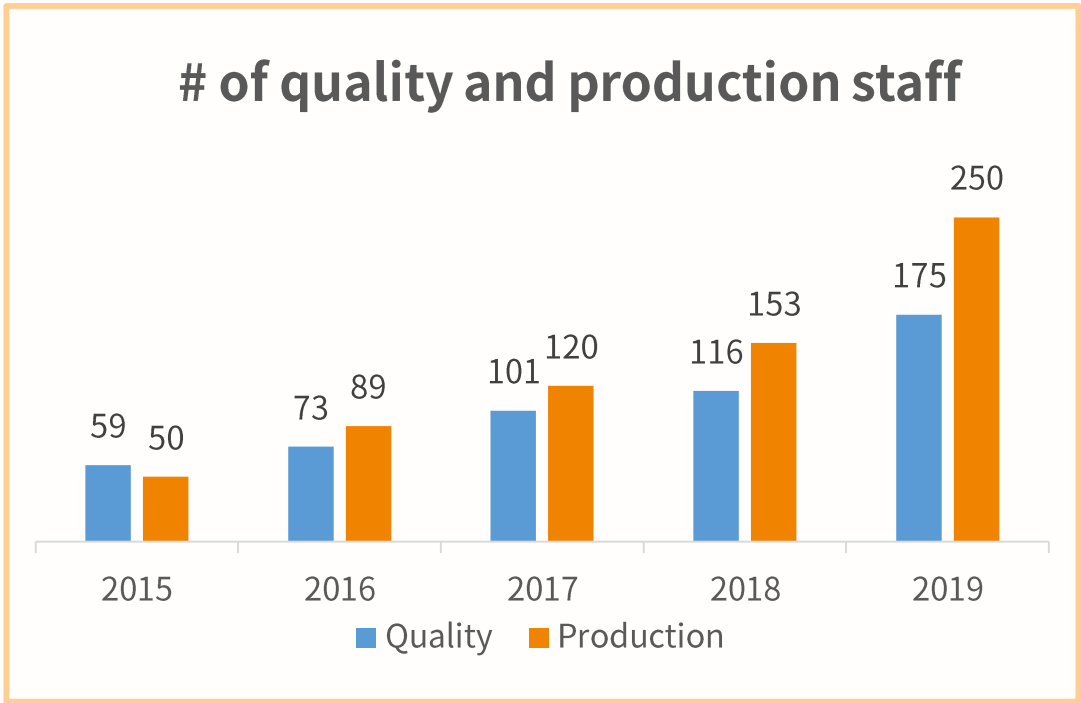
EMA SA Meeting	CTA Approval	MAA Accepted by EMA	EMA GCP Inspection	EMA GMP Inspection	Pass GCP Inspection	Pass GMP Inspection
2016.06	2017.05-09	2019.06	2019.10-2020.01	2019.12	2020.03	2020.04

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

Quality Management System



175 staff in quality management team, with a ratio of 7:10 compared with staff in production and operation team.



Based on “Good Manufacturing Practice”（revised in 2010), Henlius established drug quality management system using global standards and ensured production of high quality drugs.

1.4 Successful Inspection Results with High Standard Quality System

Inspection Org	External 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	- IND 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 Has Been Demonstrated by Previous Deals

	Acquirer	Owner of Manufacturing Facility	Facility Information	Acquisition Time	Deal Value (USD)
1	FUJIFILM Value from Innovation	Biogen	■ **Deal Location**：Denmark ■ **Capacity**： - 6 X 15,000L Bioreactors ■ **Certification**：EMA	2019	~$890M
2	Catalent CONSUMER HEALTH	COOK PHARMICA	■ **Deal Location**：USA ■ **Capacity**： - 2 X 2,500L Bioreactors - 1 X 600L Bioreactor - Multiple 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

Globalization Strategy

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

- **China's first** biosimilar with global multi-center Phase 3 clinical trial (2017-2019)
- **China's first** trastuzumab developed based on "Guiding Principles of Biosimilars" with NDA accepted by NMPA (2019.04)
- **China's first** domestic mAb biosimilar to file NDA (2019.06) in EU as well as the first "Chinese" trastuzumab to receive EU GMP certificate (2020.04)

2010 — Benchmarking EU standard from pre-IND development

2015 — Manufacturing facility and quality management system passing EU QP inspections

Built Global standard manufacturing facility

2016 — Commenced global multi-center Phase 3 Clinical Trial

Being China's first biosimilar to start global clinical trials, obtained Phase 3 clinical trial approval in **China, Ukraine, Poland and Philippines,** enrolling 608 patients

2017 — Executing oversea licensing agreement with well-known pharmaceutical companies

2017-2018

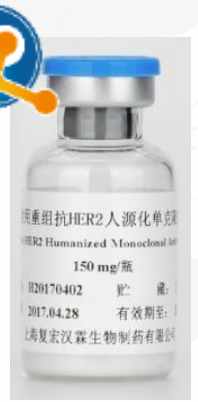
accord
Pan Europe & MENA

Jacobson Pharma Corporation
Hong Kong & Macau

Cipla
Australia, NZ, Malaysia, Columbia

mAbxience
Argentina, Uruguay, Paraguay (2020.03)

2019 — Filed NMPA NDA Filed EU MAA Negotiating more oversea collaborations



2020.02 — Research on HLX02 similarity published on international journal of *Biodrugs*

2020.04 — GMP certificate received

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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**

Data source：Company announcement

2.3 EU GMP Approval Is an Important Step for Us to Establish Strong Global Commercialization with Our Strategic Partners

- Exclusive licensing and commercial rights of rituximab (HLX01) in **Colombia, Peru, Ecuador** and **Venezuela**
- Exclusive commercial rights of PD-1 (HLX10) in **Philippines, Indonesia, Malaysia, Singapore, Thailand, Laos, Myanmar, Cambodia, Brunei and Vietnam**
- Exclusive commercial rights of trastuzumab (HLX02) for over 70 jurisdictions and regions in **Europe, MENA, North Africa and CIS**

- Exclusive commercial rights of rituximab (HLX01) in **Argentina, Paraguay, Uruguay and Bolivia**
- Exclusive commercial rights of trastuzumab (HLX02) for **Argentina, Uruguay, and Paraguay**
- Exclusive commercial rights of trastuzumab (HLX02) for **Hong Kong and Macau**
- Exclusive commercial rights of trastuzumab (HLX02) for **Australia, New Zealand, Colombia and Malaysia**

Jointly advance product commercialization of HLX01/03 in the PRC with Fosun Pharma

- Exclusive commercial rights of rituximab (HLX01) and adalimumab (HLX03) in the PRC

Benefit from Fosun Pharma:

- Decades of market experience and know-how in a changing Chinese healthcare industry
- Superior market access ability, providing comprehensive coverage for product portfolio
- Extensive sales network covering both higher and lower tier markets, penetrating deeply nationwide

Self-managed sales team is in charge of China sales of HLX02 (trastuzumab) and following products

- 100+ clinical study sites，5+years of clinical trial experience and access to a comprehensive KOL and physician network
- Assemble a sales team of 400-500 staff during the year

Note：as of March 31, 2020

Review and Outlook

3.1 Henlius Is Committed to Helping Domestic and Overseas Patients with Global Quality

- **Successful launch of HLX02 is a key focus of 2020, will become an engine and a cornerstone of Henlius commercialization**

- **Enhance manufacturing capacity:**
  - Accelerate capacity **optimization** and **maximization**, as well as build brand image of **"Made by Henlius, International Quality"**
  - 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 of Henlius

- **Optimize commercial operation:**
  - Sales team management
  - Market penetration
  - Access (pricing strategy, payment plan etc)

- **Business development:**
  - Achieve synergy with Fosun Pharma via strategic partnership on product development
  - Actively seek domestic and overseas BD opportunities, including product license-out, joint-venture, and etc.

- **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 on March 30, 2020 (see previous announcement)	

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Reliable Quality | **Affordable** Innovation