

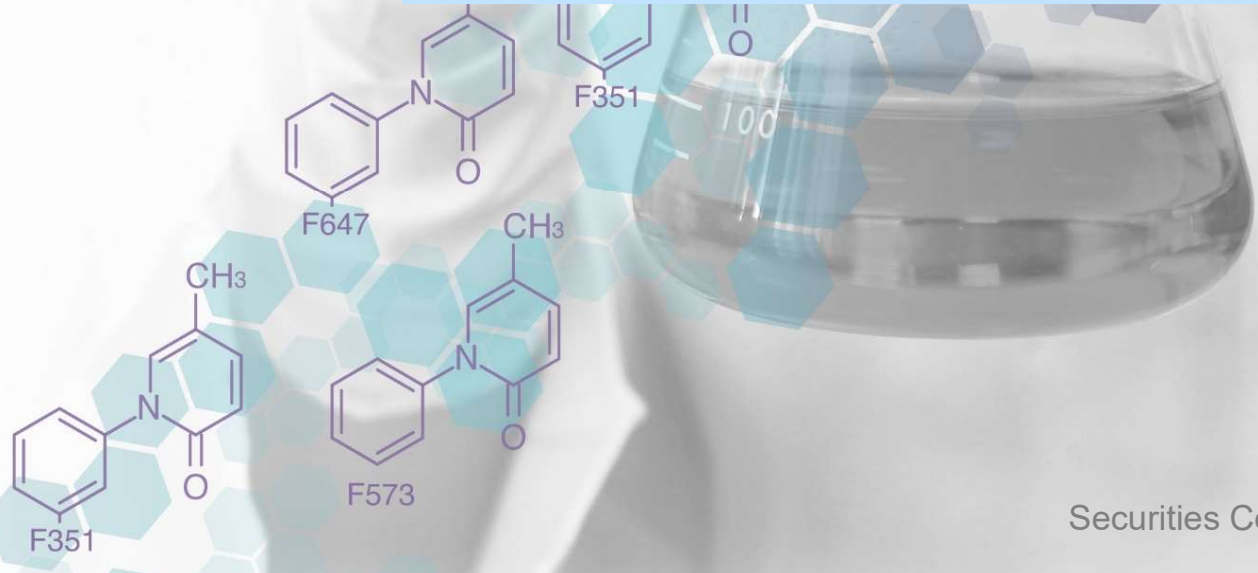


GNI Group Ltd.

Q3 FY2020 Financial Results  
Corporate Presentation

November 16, 2020

We Bring New Hope to Patients



## Forward-looking Statements

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This English summary translation is for convenience only. To the extent there is any discrepancy between this English translation and the original Japanese version, please refer to the Japanese version.

## FY2020 – Q3 Highlights

### Continuous growth despite global pandemic

We continued executing our business plan smoothly in Q3 and achieved year over year revenue and profit growth, while investing heavily into R&D for our future growth. Consolidated revenue increases by 30.4% and consolidated profit by 21.9% on a year over year basis.

#### **Pharmaceutical Sector** (*\*Pharmaceutical Segment is used in Tanshin*)

Etuary® sales in the cumulative Q3 FY2020 under review were strong at 46.0% increase year over year.

#### **Biomaterial Sector** (*\*Medical Device Segment is used in Tanshin*)

COVID-19 still affected the U.S. healthcare industry in Q3, with many hospital suspending elective surgical procedures and impacting key clients of our biomaterial business, which resulted in decrease of revenue by 13.8% and segment profit by 37.9% on a year over year basis.

#### **Healthcare Products Sector** (*\*stated as Healthcare business under Pharmaceutical Segment*)

Sales of our healthcare related business [non-core] in China showed ongoing strong growth resulting from increasing demand during pandemic.

# FY2020-Q3 Consolidated Financial Results Comparison (YoY)

Million yen : Amounts of less than one million yen are rounded down

| Statement of Income                                | FY2019<br>Jan.-Sept. | FY2020<br>Jan.-Sept. | Change |
|--|----------------------|----------------------|--------|
| <b>Revenue</b>                                     | 5,333                | <b>6,953</b>         | 30.4%  |
| <b>Gross profit</b>                                | 4,683                | <b>5,828</b>         | 24.4%  |
| Selling, general and administrative expenses       | △3,024               | △3,495               | 15.6%  |
| Research and development expenses                  | △557                 | △855                 | 53.6%  |
| <b>Operating profit</b>                            | 1,081                | <b>1,411</b>         | 30.6%  |
| Finance income                                     | 31                   | 40                   | 26.4%  |
| Finance costs                                      | △160                 | △72                  | △54.9% |
| <b>Profit before tax</b>                           | 952                  | <b>1,379</b>         | 44.8%  |
| Income Tax expense                                 | △216                 | △482                 | 122.6% |
| <b>Quarterly profit</b>                            | 735                  | <b>897</b>           | 21.9%  |
| <b>Profit attributable to owners of the parent</b> | 280                  | <b>466</b>           | 66.7%  |
| Statements of Financial Position                   | As of Dec. 31, 2019  | As of Sept. 30, 2020 | Change |
| <b>Cash and cash equivalents</b>                   | 7,674                | <b>8,569</b>         | 11.7%  |

\* Differences due to rounding

## Revenue & Gross Profit

Continued strong performance of the pharmaceutical business in China driving revenue and gross profit growth

## SG&A expenses

Maintaining a focus on effectively managing expenses and improving margins

## R&D expenses

Increase in R&D numbers represent ongoing commitment to invest in our drug development and clinical trial activities

## Operating profit

Keeping our operational profit margin at the 20% range while maintaining growth of sales

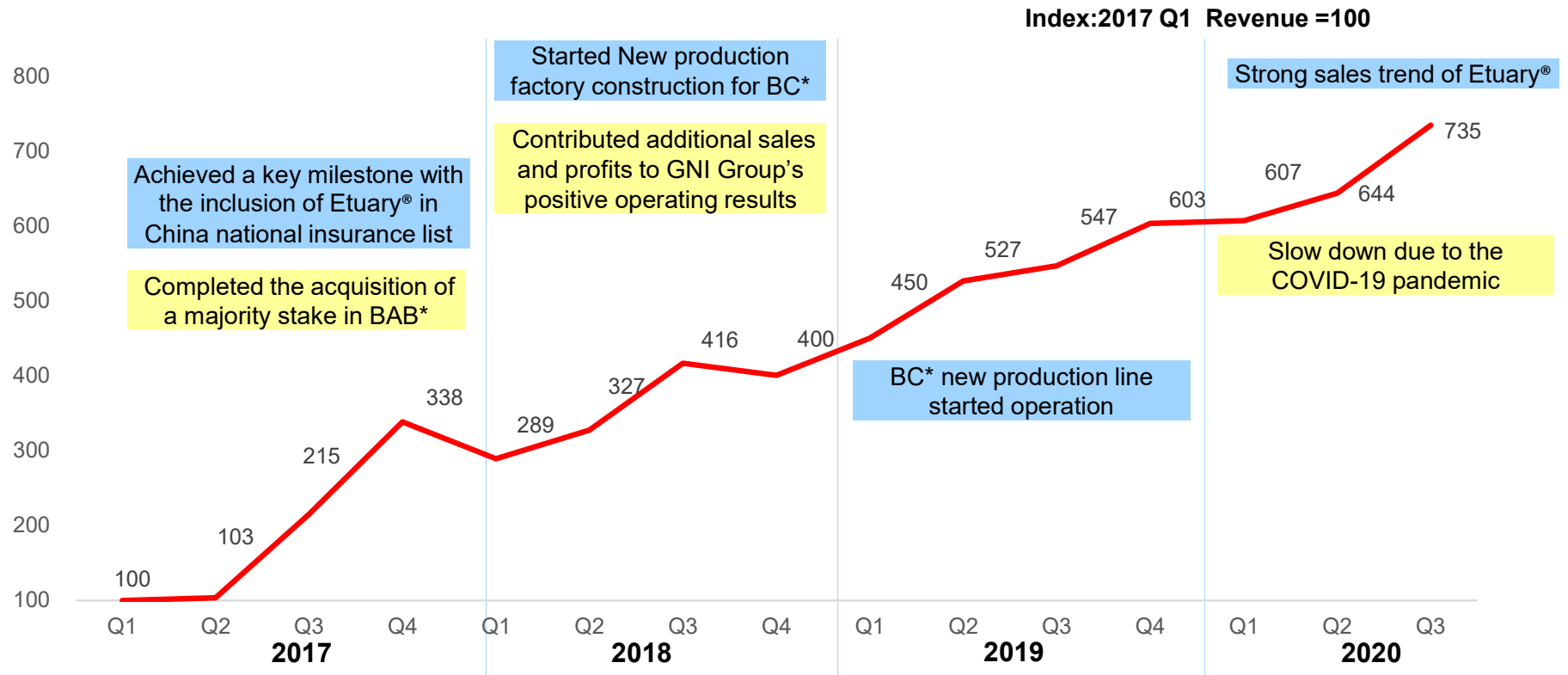
## Quarterly Profit

Stable quarterly profit margin while increasing R&D activities

## Profit Attributable to Parent

Improved profit attributable to parent

# Revenue Growth Trend



**Pharmaceutical Business: China**  
**Medical Equipment Business: US**

BC : Beijing Continent  
 BAB : Berkeley Advanced Biomaterials LLC

## Development : Pipeline Update

| Product - Indication  | Origin      | Phase I | Phase II | Phase III | Latest Status  |
|---|-------------|---------|----------|-----------|--|
| <b>Etuary® (China)</b>  |             |         |          |           |  |
| - <b>Connective Tissue Disease Associated Interstitial Lung Disease (CTD-ILD)</b> | Proprietary |         |          |           | Dual Phase III clinical trials ongoing. Proceeding smoothly despite the delay caused by the spread of COVID-19 infection.              |
| - <b>Radiation Pneumonitis (RP)</b>   | Proprietary |         |          |           | Expanded RP clinical trial is ongoing  |
| - <b>Diabetic Nephropathy (DN)</b>  | Proprietary |         |          |           | Phase I clinical trial is underway on schedule   |
| - <b>Pneumoconiosis (PD)</b>  | Proprietary |         |          |           | Preparations for Phase III are underway  |
| <b>F351 (China, USA)</b>  |             |         |          |           |  |
| - <b>Liver Fibrosis (China)</b>   | Proprietary |         |          |           | Phase II data disclosed. See detailed information on Page 7  |
| - <b>Liver Fibrosis (USA)</b>   | Proprietary |         |          |           | See detailed information on Page 7   |
| <b>F573 (China)</b>   |             |         |          |           |  |
| - <b>Acute/Acute-on-chronic Liver Failure</b>                                     | License-in  |         |          |           | Phase I clinical Trial protocols were approved by Union Hospital. Applying to HGRAC (Human Genetics Resources Administration of China) |

*Tamibarotene will be resumed in Japanese version in order to avoid asset impairment discussion*

## F351-The Key to our Future

### Completion of Phase 2 Clinical Trials of F351

- F351 Phase II clinical trials for the treatment of HBV induced liver fibrosis met primary endpoints of reduction of liver fibrosis score (Ishak Score)
- F351 showed good safety profile among liver fibrosis patients

### Regulatory Path Forward

- Submitted NDA application for API of F351 to CDE of NMPA (disclosed)
- Preparing consulting CDE of NMPA for
  1. Whether application for early approval for use in limited group of patients is allowed
  2. How to proceed onto Phase 3 trial with or without early approval
  3. How to expand to other important organ fibrosis
  4. All decisions are up to CDE
- Consult with US FDA on how to conduct Phase 2 trial in US

## Beijing Continent's Growth Path

### ■ Preparation for bigger capacity

Acquired the land in Hebei Province (approximately 13,000 square meters) adjacent to the current factory

- Strong sales trend of Etuary® expected
- F351 production

### ■ Expanded pipeline

GNI Group transferred certain intellectual property rights such as F351 for liver fibrosis, F528 for Chronic Obstructive Pulmonary Disease (COPD), and F230 for Pulmonary Arterial Hypertension (PAH) to BC. Transfer of F351 IP is a necessary step in any future NDA application.

### ■ IPO on track

Preparing for IPO in 2021 at either Shanghai STAR Market or Shenzhen ChiNext

- Increase brand recognition in the Chinese pharmaceutical industry
- Flexibility in financing and M&A opportunities
- Investment return for all shareholders including GNI



## IR Hot Topics (Q&A Session in J Page)

- **Timeline for F351 NDA and Phase III trials**

We are actively preparing for consulting with CDE of NMPA as explained previously. All decisions are up to CDE. Although we cannot decide the timeline, we will disclose any material progress in the coming months.

- **How do you decide in-house or alliance with a partner for F351 Phase II in the US. Any possibility of capital increase?**

Among biotech companies in the world, GNI is a rare one which can carry out drug discovery research while generating profit. We intend to keep our operation in this way. If we raise any capital in the future, we will be looking for one or more of the factors: a) stabilization of shareholder structure b) near-term benefits to the company c) minimized dilution d) strategic synergy. At this moment, we have no plan to raise money in Japan for large scale F351 clinical development in US yet, which tends to be costly.

- **When will the medical papers and conference be made for F351 Phase II results?**

We are in the middle of preparing a draft. It should come out in 2021 after we file additional patents to protect our key findings.

- **How to reduce volatility? Any intent to move to TSE 1<sup>st</sup> section**

GNI shares has been actively traded in recent years, sometimes unrelated to the fundamentals of the company. We have nearly 10,000 shareholders which reflect people's enthusiasm and interest toward our business. We will continue to do timely disclosure of material news to repel any market rumor or misunderstanding. We have also been actively studying the possibility of moving to the 1<sup>st</sup> section of TSE or other method to attract stable large shareholders.

## IR Hot Topics (Q&A Session in J Page)

- **Why did we have to transfer it from SG to BC?(the purpose)**

As part of future NDA application, BC as the only manufacture center in whole GNI Group, need to have the IP.

- **How much did BC pay for this matter? (the value of IP)**

Transfer will NOT affect consolidated revenue because all revenue of BC has been counted in the GNI consolidated financial statement.

- **Is there any change of benefit to our Group? (influence to the current PL and the future PL, including after IPO of BC)**

Transfer will likely positively affect profit attributable to parent company in 2020 and beyond (pls confirm with Tom & Ruoyu). But detailed numbers will need to be confirmed with audit firms. There are some disputes here.

# Contact Information

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