PRESS RELEASE

Biocon Q1FY21 Revenue Rs 1,690 Cr, Up 14%; EBITDA at Rs 432 Cr; Net Profit (from continuing ops) at Rs 153 Cr Generics up 16% at Rs 599 Cr, Biosimilars up 19% at Rs 692 Cr

Bengaluru, Karnataka, India: July 23, 2020:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fiscal first quarter ended June 30, 2020.

Commenting on the results, ***Kiran Mazumdar-Shaw, Executive Chairperson****, said: "Our consolidated revenue for Q1FY21 stood at* ***Rs 1,690 Crore****, recording a strong growth of* ***14%****, driven by robust performances by the* ***Biosimilars*** *and* ***Generics*** *business segments which grew by* ***19%*** *and* ***16%****, respectively. The* ***Research Services*** *business reported flat revenue growth at* ***Rs 422 Crore*** *due to slowdown of operations impacted by the COVID-19 crisis. EBITDA for the quarter stood at* ***Rs 432 Crore*** *and EBITDA margin was at* ***26%****. Net Profit (from continuing operations) was at* ***Rs 153 Crore****. Profitability for the quarter was impacted due to higher R&D spend, lower profit share in the Biosimilars business, and lower profitability in the Research Services segment."*

*"****It has been a breakthrough quarter for Biocon as we made a significant contribution to the global efforts aimed at addressing the pandemic through our innovative science****. Earlier this month, the* ***Drugs Controller General of India*** *(DCGI) granted 'restricted emergency use approval' for* ***Itolizumab****, our novel anti-CD6 biologic therapy for the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS). The* ***'proof of concept' pivotal study data is encouraging and highlights the urgent importance of further evaluating the potential therapeutic efficacy of Itolizumab in a larger number of COVID-19 patients****. As a part of our commitment to the DCGI, we have planned* ***a 200-patient, pan-India Phase IV trial to be conducted across 10-15 hospitals*** *with a high caseload of serious COVID-19 patients. The study protocol has been submitted to the DCGI and we will commence the trial soon."* ***she added.***

BUSINESS HIGHLIGHTS

BIOSIMILARS: Biocon Biologics

- Received **U.S. FDA approval** for biosimilar **Insulin Glargine**, **Semglee,** making it the third product under the Biocon / Mylan collaboration to be approved in the U.S.

- Partner Mylan received U.S. FDA approval for **biosimilar Adalimumab**, **Hulio**, in which Biocon Biologics has shared economic interest
- Received the **Certificate of GMP Compliance** from **EMA** for multiple Biologics drug substance and drug product manufacturing facilities at Biocon Park, Bengaluru

GENERICS:

- Signed an agreement with DKSH Business Unit Healthcare under which DKSH will sell and distribute **seven of Biocon Pharma's generic formulations** in **Singapore** and **Thailand**.

NOVEL BIOLOGICS

- **Itolizumab**, our '**first in class' anti-CD6 monoclonal antibody**, received 'restricted emergency use approval' from DCGI for treating cytokine release syndrome (CRS) in moderate to severe acute respiratory distress syndrome (ARDS) patients due to COVID-19

- **Bicara Therapeutics**: Its lead asset, BCA101 has entered the clinic in the US. First patient dosed with BCA101 (anti EGFR-TGFbRII fusion mAb) under a U.S. IND

RESEARCH SERVICES: Syngene

- Signed a **voluntary license agreement with Gilead** to **manufacture** and **supply Remdesivir** in India and 127 other countries
- **Indigenously developed ELISA** testing kit, has been outsourced to a partner for manufacturing and distribution across the country
- **RT-PCR testing facility** has supported government hospitals across Karnataka by conducting more than 30,000 COVID-19 tests free of charge.

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY21

In Rs Crore

Particulars	Q1FY21	Q1FY20	Growth
INCOME			
Generics	**599**	516	**16%**
Biosimilars	**692**	582	**19%**
Novel Biologics	**-**	-	**-**
Research Services	**422**	421	**0%**
Inter-segment	**(41)**	(60)	**(32%)**
Revenue from Operations#	**1,671**	1,459	**15%**
Other Income	**18**	24	**(24%)**
TOTAL REVENUE	**1,690**	**1,483**	**14%**
EBITDA	**432**	462	**(6%)**
PBT	**252**	321	**(21%)**

Net Profit *(before exceptional item and discontinuing operation)*	**153**	231	**(34%)**
Loss from discontinuing operation	**4**	8	**(54%)**
Exceptional item, net of taxes	-	(17)	**(100%)**
Net Profit	**149**	206	**(28%)**
R&D Expenses in P&L	**107**	79	**35%**
Gross R&D Spends	**142**	110	**29%**
EBITDA Margin	**26%**	31%	
Core EBITDA Margin	**32%**	36%	
Net Profit Margin	**9%**	14%	
#includes Licensing Income net of tax	**10**	7	

Notes: Figures above are rounded off to the nearest Cr; % based on absolute numbers.

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q1FY21

- **Q1FY21 Consolidated Revenue** grew **14%** to **Rs 1,690 Crore** from Rs 1,483 Crore in Q1FY20.
- **Q1FY21 Earnings before Interest, Depreciation and Amortization (EBITDA)** was **Rs 432 Crore** (vs. Rs 462 Crore in Q1FY20)
- **Q1FY21 Net Profit** (from continuing operations)* was at **Rs 153 Crore** (vs. Rs 214 Crore in Q1FY20).
- **Q1FY21 Net Profit** was at **Rs 149 Crore** (vs. Rs 206 Crore in Q1FY20)

*Note: The Group is in process of disposing off its JV entity and related UAE operations. Accordingly, share of profit / (loss) from the JV and results of its related business have been disclosed as discontinuing operations in the consolidated financial results.

BUSINESS SEGMENT REVIEW: Q1FY21

Realignment of Segmental Reporting: Post completion of Group restructuring in FY20, the operating segments have been realigned effective April 1, 2020. Branded Formulations India business has been merged with Biosimilars and Novel Biologics has been carved out as a separate business segment. As a result, **the four new Operating Segments are Generics, Biosimilars, Novel Biologics and Research Services.**

GENERICS: APIs & Generic Formulations

- Q1FY21 Revenue at **Rs 599 Crore**, up 16% (YoY) from Rs 516 Crore in Q1FY20

The **Generics** business reported a revenue growth of **16%** for the quarter at **Rs 599 Crore**. The Generic Formulations business in the U.S. was the main driver of this growth with the formulations

commercialized under our own label maintaining a steady high-teens market share. This was supplemented by the API business, which witnessed a higher than normal demand of certain key APIs such as statins and immunosuppressants in key geographies as customers picked up stocks to ensure continued ability to serve patient needs.

Commenting on the performance, **Siddharth Mittal, CEO & Managing Director, Biocon Ltd,** said, *"The intensified focus on our Generics business over the past year is showing results. Despite the challenging environment of the global pharmaceutical industry, this business reported a **16%** increase in revenue to **Rs 599 Crore** in Q1FY21, continuing to deliver the strong double-digit growth momentum witnessed over the past several quarters. The performance was led by the Generic Formulations business, which reported robust growth in the U.S. We also witnessed good traction in our key APIs during the quarter. Additionally, we expanded the commercial footprint of our Generics Formulations business by partnering with DKSH to commercialize seven of Biocon Pharma's generic formulations in Singapore and Thailand."*

Biocon's subsidiary **Biocon Pharma** Ltd and **DKSH** Business Unit Healthcare signed an agreement under which DKSH will sell and distribute seven of Biocon Pharma's generic formulations in Singapore and Thailand. Under the terms of the agreement, DKSH will gain an exclusive license to register and commercialize these seven generic formulations from various therapeutic areas like diabetology, cardiology, oncology and immunology, which will be sold under Biocon's brand in Singapore and Thailand. DKSH will manage marketing and sales as well as logistics for Biocon Pharma, helping drive sales growth through its capabilities and strengths in the medical and pharmacy channels.

During Q1FY21, we built on our good track record of **quality and compliance** with several key inspections, including those conducted by the U.S. FDA. Our Generic APIs manufacturing facility at Biocon Park, Bengaluru received the EIR (Establishment Inspection Report) with a VAI (Voluntary Action Indicated) status from the U.S. FDA in May for the pre-approval and GMP inspection conducted in January.

BIOSIMILARS: Biocon Biologics

- Q1FY21 Revenue at **Rs 692 Crore** up **19%** (YoY) from **Rs 582 Crore** in Q1FY20
- Segment EBITDA for Q1FY21 stood at **Rs 195 Crore**
- Patients reached through our biosimilars, Q1FY21 *(MAT)*: **2.9 million**[#]

The **Biosimilars** segment reported a strong growth of **19%** to **Rs 692 Crore** in Q1FY21 **driven by robust performance across Most of the World (MoW) markets and steady sales of our key biosimilars in U.S. and Europe, aided by a spillover of revenues from the previous quarter.**

During the quarter, we saw increased demand particularly in LATAM and AFMET regions. With a strong presence in most of the Top 20 MoW markets and with additional approvals across Latin America and CIS, we see significant acceleration and potential for biosimilar penetration in MoW markets.

Commenting on the performance, **Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics India Ltd,** said, *"We have started FY21 on a very strong note, with the Biosimilars business recording quarterly revenue of **Rs 692 Crore** with a growth of **19%** and a segment EBITDA of **Rs 195 Crore**. We have delivered on our promise of recovery in Q1FY21 over Q4FY20 with a sequential growth of **60%**."*

*"One of the highlights of the quarter was the **U.S. FDA approval for Semglee**, which will enable us to expand patient access to our Insulin Glargine through our partner Mylan. We are also pleased with **our global collaboration** with **Voluntis** for **Insulia®**, a unique digital therapeutic solution that has U.S. FDA clearance and a CE mark to help manage the treatment of Type- 2 diabetes, much needed to enable better patient outcomes and reduce costs to healthcare systems. **Biocon Biologics** will be one of the first companies globally to pair this innovation with its insulin products for the benefit of people with diabetes**. **We remain committed to impact 5 million patient lives** and attain a revenue milestone of **USD 1 billion** in **FY22**,"* **she added.**

Product Approvals

We received **U.S. FDA approval** for **Semglee**, **biosimilar Insulin Glargine 100 IU/mL** co-developed with Mylan, in June. It **marks a significant milestone** in the journey of making insulin-based therapy increasingly accessible for people with diabetes globally. **Semglee is the third product** under the Biocon/Mylan collaboration to receive FDA approval. It also makes **Biocon Biologics the first company** from India to **have received approval for three biosimilars** in the U.S. We look forward to addressing the needs of people with diabetes with the imminent launch of Semglee in the U.S.

Mylan recently received **U.S. FDA approval** for **biosimilar Adalimumab**, **Hulio,** in-licensed from a third party. Biocon Biologics **will receive an economic benefit** when Mylan launches the product. **Biosimilar Etanercept**, in-licensed by partner Mylan from a third party for Europe and other markets, also **received approval in the EU** in Q1FY21 and is expected to be launched in Europe later this year. **Biocon Biologics** retains its **economic interest in this arrangement** vis-a-vis Mylan in accordance with the existing collaboration agreement.

Key Product Updates

Our **biosimilar Pegfilgrastim**, **Fulphila**, co-developed with Mylan, has maintained a steady market share despite increasingly competitive dynamics in the U.S. During the quarter, Fulphila was launched in several key countries in **Europe.**

Ogivri, our **biosimilar Trastuzumab** co-developed with Mylan, witnessed **a positive trend in market share** in the **U.S.** in Q1FY21. Mylan is building long-term capabilities among physicians, payors and hospitals, and this is expected to strengthen over time as our partner continues to penetrate the business across customer segments.

Regulatory Updates

Our biosimilar **Bevacizumab**, co-developed with Mylan, is **under review** both by the U.S. FDA and EMA.

On the insulins front, we **continue to work with the U.S. FDA** on the independent development program of **rh-Insulin** for the market, in line with the draft guidance for **insulin biosimilars** under the **351(k) pathway**. Together with our partner Mylan, we are also **on track** with the co-development of biosimilar **Insulin Aspart.**

We target to have at least eight of our biosimilars available in developed markets through our partner by the end of FY22 viz. *Trastuzumab, Pegfilgrastim, Adalimumab, Bevacizumab, Etanercept, Insulin Glargine, Insulin Aspart and rh-Insulin^*, addressing an estimated market opportunity of up to USD 33 billion*. Our pipeline is expected to **deliver three additional molecules** between FY23 and FY25.

Manufacturing Expansion

Our **new manufacturing facility** for Pegfilgrastim drug substance in Bengaluru **received EU GMP** and **Health Canada approvals** in Q1FY21. We also received the **EU GMP Certificate** for our **drug substance** and **drug product** manufacturing facilities for Bevacizumab.

New Partnerships

In line with our aspiration to constantly innovate to transform healthcare and impact patient lives, we have entered into a global collaboration with Voluntis, a leading player in the digital therapeutics. Through this partnership, **we will develop and offer a U.S. Food and Drug Administration-cleared and CE-marked, highly validated digital therapeutic product**, **Insulia®**, to people on our insulins enabling them to better manage their diabetes. This **unique paring of products** is expected to **lead to better health outcomes and enhanced quality of life for patients** and an **overall reduction in healthcare costs**. This exclusive licensing agreement will make Biocon Biologics, one of the first companies to offer this unique digital therapeutic to Type 2 diabetes patients across the world.

Our Branded Formulations – India business has also joined the fight against COVID-19. It has **repurposed its novel biologic ALZUMAb® (Itolizumab)**, which was launched earlier in July post receiving 'restricted emergency use approval' from the DCGI for treating cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS). We had previously received the **DCGI's 'emergency use' approval for an in-licensed unique device CytoSorb®**, which is also U.S. FDA-approved and reduces CRS in critically ill patients admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure.

**Combined annual sales of originator brands ^rh-Insulin is outside of Mylan partnership*
#Moving 12-month patient population (July 2019 to June 2020)

NOVEL BIOLOGICS

Itolizumab (ALZUMAb®) - Breakthrough Therapy for Cytokine Release Syndrome (CRS) in COVID-19@

Biocon's **'first-in-class'** anti-CD6 monoclonal antibody, a novel biologic, **Itolizumab**, received the **DCGI's nod for its restricted emergency use in treatment of CRS in moderate to severe ARDS patients due to COVID-19, based on the results of a pivotal Phase II clinical study**. A multi-centric, open label, two-arm randomized pivotal clinical trial was conducted in 30 eligible patients at four hospitals across Mumbai and New Delhi. Twenty patients received Itolizumab plus best supportive care in the test arm, while 10 patients received best supportive care alone in the control arm. **The primary endpoint was mortality at the end of one month.**

At the end of the treatment period, Itolizumab demonstrated statistically significant advantage over the control arm in one-month mortality rate. All 20 patients on drug arm who were administered Itolizumab improved or were stable after Day 14 onwards. Whereas three out of ten patients in the control arm with best standard of care died while seven recovered. **Key efficacy parameters of lung function** such as PaO2 and SpO2 (oxygen saturation) improvement without increasing FiO2 (oxygen flow) **also showed statistically significant advantage for the Itolizumab arm over the control arm. All patients on the Itolizumab arm were weaned off oxygen by Day 30, and none needed ventilator support unlike the control arm.**

Key secondary endpoints of clinical markers of **inflammation** such as IL-6, TNF-α, serum ferritin, d-dimer, LDH and CRP **showed clinically significant suppression post Itolizumab dosing and correlated well with clinical improvement in symptoms and chest X-ray images.**

Itolizumab was overall well tolerated and found to be safe. The infusion reactions in some patients were manageable with slowing down the infusion rate.

As a part of our commitment to the DCGI, **we have planned a 200-patient, pan-India Phase IV trial to be conducted across 10-15 hospitals** that have a high caseload of serious COVID-19 patients. The study protocol has been submitted to the DCGI and we will commence the trial soon.

The results from the Phase IV trial will create a larger body of evidence for efficacy of Itolizumab in COVID-19 complications, which will be included in our research publications.

Based on the encouraging study results, our U.S.-based partner, Equilllium is planning to conduct a global randomized controlled clinical trial of Itolizumab in COVID-19 patients for which it will file a U.S. investigational new drug application (IND) soon.

Our Cuban partner**, Centre of Molecular Immunology**, has also reported encouraging results from a clinical trial with Itolizumab in 76 COVID-19 patients in Cuba. At the end of the trial, 79% of severely ill patients were discharged from the ICU after 14 days of treatment, while moderately ill patients showed a reduction in the rate of disease progression.

Others

Bicara Therapeutics, our Boston-based wholly owned subsidiary focused on developing novel immuno-oncology assets, reported that its lead asset has entered the clinic in US and the first patient has been dosed with the fusion monoclonal antibody, BCA101, which is a first-in-class compound that targets both EGFR with TGFβ.

This follows a successful Investigational New Drug (IND) application under which the U.S. FDA has allowed Bicara to proceed with its Phase 1/1b, open-label study of the safety and tolerability of BCA101 alone and in combination with Pembrolizumab in patients with EGFR-driven advanced solid tumors.

RESEARCH SERVICES: Syngene

- Q1FY21 Revenue at **Rs 422 Crore** versus Rs 421 Crore in Q1FY20

Research Services revenue for the quarter stood at **Rs 422 Crore** for Q1FY21, driven by steady performances in the Discovery Services and Dedicated Centres businesses.

The national lockdown resulted in a temporary suspension of operations in all divisions. Since restarting, the expansion of shift working and other protection measures for employees allowed the divisions to return to near normal levels of operation and get client projects largely back on schedule.

Commenting on the performance, Jonathan Hunt, CEO & Managing Director, Syngene said: *"In line with our guidance, Q1FY21 revenue was flat at **Rs 422 Crore** compared to the same quarter last year due to the temporary suspension of operations during the nationwide lockdown. However, the implementation of protective measures allowed all divisions to restart gradually and operate at close to normal levels for the last six weeks of the quarter. Across the Company, our teams have worked hard to get projects back on schedule. Overall Q1FY21 performance was as expected and we look forward to returning to growth in Q2FY21."*

Syngene is actively engaged in various COVID-19 research and diagnostic projects. It has indigenously developed an **ELISA testing kit**, which has been outsourced to a partner for manufacturing and distribution across the country.

The Company has repurposed one of its high-end laboratories to **conduct RT-PCR tests** for COVID-19. It has conducted more than **30,000 tests free of charge**, for the government hospitals across Karnataka.

Syngene has also signed a **voluntary licensing agreement** with **Gilead** to **manufacture and supply Remdesivir** in India and 127 other markets.

Enclosed: Fact Sheet – with Financials as per IND-AS

About Biocon Limited:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized

novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as generic formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development.

Biocon Limited's subsidiary Biocon Biologics India Limited is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. Building on the four pillars of Patients, People, Partners and Business, Biocon Biologics is committed to transforming healthcare and transforming lives. Biocon Biologics is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a platform of 28 biosimilar molecules across diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, of which three have been commercialized in developed markets like EU, Australia, United States, Canada and Japan. It aspires to benefit 5 million patient lives with its biosimilars and attain a revenue milestone of USD 1 billion in FY22. www.biocon.com Follow-us on Twitter: @bioconlimited

FOR MORE INFORMATION	
MEDIA RELATIONS **Seema Ahuja** **Sr. VP & Global Head of Communications and Corporate Brand** ☎+91 80 2808 2222 ✆ +91 99723 17792 ✉ seema.ahuja@biocon.com	**INVESTOR RELATIONS** **Saurabh Paliwal** **Head, Investor Relations** ☎ +91 80 6775 2040, 2808 2040 ✉ investor.relations@biocon.com
Rumman Ahmed **Sr.Manager, Corporate Communications** ☎+91 80 2808 2223 ✆ +91 98451 04173 ✉ rumman.ahmed@biocon.com	

Earnings Call

The company will conduct a call at 9.00 AM IST on July 24, 2020 where the senior management will discuss the company's performance and answer questions from participants. To participate in this conference call, please dial the numbers provided below ten minutes ahead of the scheduled start time. The dial-in number for this call is +91 22 6280 1151. Other toll numbers are listed in the conference call invite which is posted on the company website www.biocon.com. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available from the conclusion of the call till July 31, 2020 on +91 22 7194 5757, Playback Code: 56227. Transcript of the conference call will be uploaded on the company website in due course.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

@The content of this Press Release was updated to reflect the final Clinical Study Report on Itolizumab