SCRIP
CITELINE COMMERCIAL

02 Aug 2022 | **Interviews**

Boehringer Will Go 'Wide, Broad, Fast, Strong' If Jardiance Hits CKD Bullseye

by Anju Ghangurde

Data is the new gold and Timmo Rousku Andersen, Boehringer Ingelheim's corporate senior vice-president, head of global regions, outlines in an interview the German group's efforts to shape go-to-market models driven by data and insights. He also touches on digital therapeutics and how the firm's R&D engine is pursuing deeper insights into interconnected disorders.

Boehringer Ingelheim GmbH is evaluating ways to radically advance as a data- and insights-driven company and big data across the private German group's operations, including the R&D and commercial engines, are "business-critical," a senior executive has emphasized.

In an interview with *Scrip*, BI's corporate senior vice-president, head of global regions, Timmo Rousku Andersen, said he expects to base the company's go-to-market models not on mere "experience" and "assumptions" but on data and insights generated by patients, healthcare professionals and the health system.

"That's where we have to move to. That's probably, for me, the biggest driver - let's build the right model based on insights," Andersen said in a wide-ranging interview.

With pharma's go-to-market strategy evolving, Andersen said the biggest trend he sees is that "no one-size-fits-all."

While BI may consider "digital-only" for a number of future launches in several markets, the executive emphasized the company is committed to a go-to-market approach that understands every innovative product, "maps how that fits into clinical practice, tracks what the governments and key stakeholders in the healthcare ecosystem say and listens to what patients need." (Also see "*Commercial Models Shifting As Pharma Mulls Digital-First Launches*" - Scrip, 16 Jun, 2020.)

“This is where data comes in, such that our decisions are based on insights of our operations and those generated by experts and healthcare professionals,” Andersen asserted.

The company’s investments in "Boehringer Ingelheim Dataland" – an end-to-end data ecosystem – reflects the group’s commitment to leverage data insights for business excellence and patient benefit, he added.

Obligation To Go ‘Wide, Broad, Fast And Strong’

Some of BI’s “super targeted” oncology and inflammation innovations that require engagement with a small number of specialists and super-specialists from a clinical trial and patient perspective could potentially emerge as digital only launches. But the indications are that the approach could be sharply different for the *Eli Lilly and Company*-partnered blockbuster Jardiance (empagliflozin).

Andersen indicated that if BI gets the data that it hopes on the treatment of chronic kidney disease (CKD) for Jardiance at the end of this year, the German firm could embark on a distinct journey - one he termed as a “bit daunting.”

The wider go-to-market efforts necessary given the high unmet need could require “a few thousands of people across the world” - employees and partners - to work with physicians, caregivers, nurses, delivery organizations and experts to generate real-world data and enable linkages with diagnosis and prognosis for longer term therapy. (Also see "*After Jardiance Heart Failure Successes, BI And Lilly Focus On Kidney*" - Scrip, 17 Mar, 2022.) (Also see "*What Physicians Want: Less of Promotional Content*" - Scrip, 7 Feb, 2022.)

“If our data show what we hope to see, we also have an obligation to go wide, broad, fast and strong. This can change the lives of so many patients with CKD, hence we are keen to holistically understand challenges and solve for them, while leveraging the potential,” Andersen declared.

BI’s stance is interesting, especially since big pharma was in the 90s known to deploy “armies of field forces” to cover vast territories for drugs targeting hypertension, hyperlipidemia and asthma that treated millions of patients and involved reaching large number of physicians. Peers like *Pfizer Inc.* were reported to have deployed sales "battalions" – an estimated 10,000-plus reps - in the heydays of blockbusters like Viagra (sildenafil) and Lipitor (atorvastatin).

Chronic kidney disease is a progressive condition and is estimated to affect almost 850 million people globally, which is more than one in 10 adults, and worldwide five to 10 million die each year from the ailment. It is generally more prevalent in older individuals, women, racial minorities, and in people with diabetes mellitus and hypertension, and imposes a huge burden on healthcare in low- and middle-income countries that are poorly equipped to deal with its consequences.

“If it is as broad a problem - as it is with CKD - there’s almost close to a billion people, we can go broad. But again, it's understanding the situation,” Andersen explained.

There have been significant label expansions for Jardiance in the last year, making the SGLT2 inhibitor the first drug in the class to be approved for heart failure with both reduced and preserved ejection fraction. An approval for CKD would add a whole new dimension to boost Jardiance's status as the best-selling SGLT2 inhibitor. (Also see "*Boehringer Pharma Chief Confident Of Continued Success For Jardiance*" - Scrip, 12 Apr, 2022.)

In March this year, the Jardiance Phase III EMPA-KIDNEY trial was stopped early due to “clear positive efficacy” in people with CKD, based on the recommendation of the trial’s Independent Data Monitoring Committee. The primary endpoint of EMPA-KIDNEY, which included over 6,600 adults with CKD, was a composite of kidney disease progression or cardiovascular death. The key secondary outcomes included cardiovascular death or hospitalization for heart failure, all-cause hospitalization and all-cause mortality.

It will be interesting to see how the CKD market battle unfolds if things go to plan for Jardiance, given that *AstraZeneca PLC*’s same-class rival Farxiga/Forxiga (dapagliflozin) was approved in the US last year to lower the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with CKD at risk of progression.

Johnson & Johnson’s Invokana (canagliflozin) is indicated to slow the progression of diabetic nephropathy (also known as DKD) and reduce the risk of hospitalization for heart failure in patients with type 2 diabetes, and DKD with albuminuria >300 mg/day. About 37 million people in the US are estimated to have CKD.

Digital Therapeutics

Importantly, Andersen also outlined BI’s wider approach in the area of digital therapeutics, where in 2020 it struck a collaboration with *Click Therapeutics, Inc.* to develop and commercialize CT-155, a novel prescription digital therapeutic to aid in the treatment of schizophrenia. (Also see "*BI Finds Right Fit For Digital Therapeutic Partnership With Click*" - Scrip, 11 Sep, 2020.)

On whether BI’s appetite for digital therapeutics goes beyond markets like the US and Germany, Andersen explained that regulators in those two countries are the most advanced and equipped with the expertise to get digital therapeutics and related products to the market, while India and China could potentially be the

Gut-Brain Connect: How metaMe’s Digital Therapeutic Hopes To Rewire IBS Treatment

By Anju Ghangurde

SCRIP
CITELINE COMMERCIAL

largest growth market for such therapeutics.

"Our intent is to strategically use the US and Germany as proof of concept to expand these offerings to other geographies such as India and China."

Andersen explained that in countries like India and China, which still need to make a massive jump in terms of reaching and serving more patients, digitalization could scale things sharply. "When you build the app, if one person downloads or 300 million download it, you'll have scale that you would never have had in any of these areas," he explained.

18 Apr 2022
metaMe Health CEO and ex-Takeda executive Tim Rudolphi and partner firm Indegene's senior vice president Marut Setia discuss with Scrip plans for the FDA-authorized, gut-directed hypnotherapy Regulora, including an openness to outcomes-based pricing and the wider go-to-market strategy.

Read the full article here

Last year, a report by the IQVIA Institute for Human Data Science noted that health-related mobile applications available to consumers on top app stores worldwide surpassed 350,000, with a whopping 90,000-plus digital health apps added in 2020 — an average of more than 250 apps per day.

While the majority of mobile health apps available are general wellness apps, across a sample of high-quality apps, those for health condition management were increasing and many were being developed for narrower disease segments. "Mental health, diabetes and cardiovascular disease-related apps now account for almost half of disease-specific apps," the report said.

Andersen also maintained that the reimbursement issue for digital therapeutics doesn't deter companies like BI "because when we see payment models and technologies that people are using as part of their life, [it's] an element we can add value to."

The executive also indicated that BI is building digital solutions as part of its cardio-renal-metabolic portfolio in line with its pursuit to retain world leadership in that space over the coming 10-15 years.

"We acknowledge our obligation to support patients in their treatment journey and will continue doing so."

'Looking Across Borders'

Andersen also highlighted how the BI R&D engine is pursuing deeper insights in areas like

cardio-renal-metabolic conditions, a group of interconnected disorders that affect more than a billion people globally and are a leading cause of death.

The executive explained that BI has a system and standardized processes that researches across disease areas and target organs with all the required information on opportunities for a drug.

“We call it ‘looking across borders.’ We are building an ambitious model and continue to explore the possibility of buying real-world databases to lay an even stronger foundation for our research work to look beyond, to innovate faster and become more patient centric,” he said.

Jardiance perhaps is a standout example of such efforts – originally approved as a type 2 diabetes medication, it now has the go-ahead for heart failure and holds potential in a broad range of chronic kidney diseases.

On whether BI expects to leverage some of the real-world insights to further broaden the scope of drugs like Jardiance in other related complications such as diabetic retinopathies and diabetic macular edema, Andersen noted that the German group had bought two massive databases in the UK recently.

"We are putting it into our data lake to understand whether we could see the signals of retinopathy in diabetes that we are not looking for in clinical trials. Several of these initiatives are ongoing. We may never be where we want to but the investments are laying the groundwork.”

The cardiovascular, renal and metabolic systems are closely intertwined and Andersen drew attention to the fact that if one organ suffers, the likelihood of others being affected increases exponentially.

While experts across specialties are increasingly beginning to work on the premise that bodily systems are interconnected, they face an impediment in health records not being connected; more so patients may visit different clinics and specialists for different ailments.

Andersen noted that, at a systems level, many countries have diabetes action plans as part of their health priorities, while some have cardiovascular or kidney disease policies.

“There is an urgent need to establish connections and educate stakeholders on the benefits of interconnected systems and data. While this can be a daunting task, it is also a big opportunity,” the BI executive added.

IPR Issues In India

Meanwhile, he also touched upon the critical role of protection and enforcement of intellectual property rights (IPR) in driving business confidence for foreign firms in markets like India. (Also

see "*Foreign Firms Not Fatigued In India, Game For 'New Things'*" - Scrip, 28 Mar, 2022.)

Andersen maintained that effective IP protection is the "backbone" of not only multinational companies but is also vital from a country perspective as innovation from the Indian industry matures. Neighbor and competitor China had ticked some of the right boxes on those fronts, he observed.

"You cannot advance the basic building blocks of the healthcare innovation ecosystem without protecting innovation/IPR. This is critical to ensure that patients in India have equal and timely access to innovator therapies in the long term," he added.

BI has witnessed some IPR-related turbulence in India for both Jardiance and Trajenta (linagliptin) over the recent past, though company has dealt deftly to put a lid on the infringing activity, at least for now. (Also see "*Jardiance, Trajenta Wins: Boehringer Takes Rough With Smooth In India*" - Scrip, 13 Jun, 2022.)

BI's head of global regions went on to emphasize that while there is a need for certainty around protection of innovation in the marketplace, it is imperative to also "connect the dots around all the pathways" to get to the patient and the topics of product, price, profit and protection.

"If we can get to a higher level of certainty, the risk and the opportunity of exploring access programs for patient reach through government initiatives will be much better balanced than it is today," Andersen stated.

Several years ago, India launched the Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), a non-contributory government-sponsored health insurance scheme, which enables increased access to in-patient healthcare for poor and vulnerable families in secondary and tertiary facilities.

At the time of its launch in 2018, about 500 million beneficiaries – roughly the size of the

B-Ingelheim India Chief On Strategy, Jardiance Challenge, Gender Balance In Pharma

By Anju Ghangurde

27 Oct 2021
Boehringer Ingelheim's Country Managing Director for India Vani Manja outlines how she expects to shape the German group's growth trajectory in the country, while also dealing with the unexpected pre-expiry challenge to the Jardiance patent. The executive also discusses her personal career journey, learnings from her prior role in the US and gives advice to women executives seeking to move up to the higher echelons of the corporate world.

Read the full article here

population of the EU – were expected to be covered for secondary and tertiary care at all public and empanelled private hospitals in India, making it the world's largest government-funded healthcare program by number of beneficiaries. (Also see "*Can Modicare Reshape India's Health Care Paradigm?*" - Scrip, 27 Nov, 2018.)

The pharma industry believes that AB-PMJAY has the potential to make innovative therapies available to beneficiaries across the country and has been engaging with the National Health Authority on this front.