SCRIP
CITELINE COMMERCIAL

27 Oct 2021 | **News**

Novartis CEO: Oncology Treatment Almost Back To Pre-COVID Levels

But Breast Cancer A Bit Slower

by Kevin Grogan

The Swiss major's oncology business performed well in the third quarter with Kisqali sales catching the eye despite the specific problems that the pandemic has brought for breast cancer patients.

While *Novartis AG* is seeing a strong recovery overall across most therapeutic areas following COVID-19, CEO Vas Narasimhan has told *Scrip* that the rates of diagnoses in certain cancers are still some way off pre-pandemic levels.

Speaking as Novartis posted its third quarter financials, which included $3.90bn (+6%) in sales from its oncology operations, Narasimhan said: "I would characterize it as a little mixed. In some cancers, we see a return back to normal and in others, in breast cancer in particular, we still see biopsy rates and molecular testing below pre-COVID levels."

The pandemic has certainly affected the performance of Piqray (alpelisib) for patients with HR+/HER2- advanced breast cancer with a PIK3CA mutation. In the third quarter, turnover from the drug slipped by 1% to $82m, with launches in Europe and emerging markets offset by declining sales in the US that have been impacted by fewer new patient starts, physician visits and cancer screenings due to COVID-19.

However, a breast cancer drug that continues to grow is Kisqali (ribociclib) and sales of the CDK4/6 inhibitor were up by 27% to $232m. Susanne Schaffert, president of Novartis Oncology, told analysts that the drug had achieved a market-leading position with 40% patient share in pre-menopausal patients in the EU4 (Germany, France, Italy and Spain) plus the UK, while in the US, Kisqali grew 5% driven by increased demand in pre-and postmenopausal patients, "with usage shifting to earlier lines of therapy, which is very encouraging."

SCRIP
CITELINE COMMERCIAL

She noted that with the presentation of stellar overall survival (OS) data at the European Society for Medical Oncology congress last month from the MONALEESA-2 trial, Kisqali is the only CDK4/6 inhibitor with significant OS benefit proven across three Phase III trials, adding to data from MONALEESA-7 and MONALEESA-3. Schaffert said this had given Novartis "a lot of confidence" to start the HARMONIA study, pitting Kisqali head-to-head with Pfizer's rival CDK4/6 inhibitor Ibrance (palbociclib), adding that the company is also excited about the 5,101-patient Phase III NATALEE trial testing Kisqali as an adjuvant treatment for HR+/HER2- early breast cancer; it completed enrolment ahead of schedule in the second quarter and will read out in 2022.

Novartis All Smiles After Kisqali OS Success In MONALEESA-2

By Kevin Grogan

20 Sep 2021
After the presentation of stellar long-term survival data at ESMO for Kisqali in women with HR+/HER2- advanced breast cancer, Novartis is planning to knock Pfizer's Ibrance off its CDK4/6 inhibitor perch with the help of a head-to-head trial.

Read the full article here

Narasimhan noted that the company was "still seeing some impact for treatments that involve a short stay in the hospital," including its radioligand therapy Lutathera (177Lu DOTA octreotate), sales of which inched up by 1% to $120m, and CAR-T therapy Kymriah (tisagenlecleucel), which brought in $146m (+20%).

He told *Scrip,* "It's a steady recovery and we're hopeful that through the remaining Q4, we'll get back to a fully normal position across all cancer types and we'll start next year from a strong footing."

Keeping Faith With Canakinumab

Narasimhan also offered up a strong defence for Novartis's decision to continue looking at canukinumab as a potential treatment for non-small cell lung cancer, with the anti-inflammatory agent having just failed in a second Phase III trial.

He noted that the failed CANOPY-1 and CANOPY-2 trials were in the metastatic settings, with patients who experienced their disease re-emerge after surgery and treatment, "a challenging setting." Rather than throwing in the towel, Novartis is continuing with CANOPY-A, a Phase III study investigating canakinumab as an adjuvant therapy (after surgery), and CANOPY-N, a Phase II trial in the neoadjuvant setting, ie, before surgery.

In CANOPY-A, "these are patients who have had surgical resection of their cancers, been treated

with chemotherapy and are now trying to avoid the recurrence of cancer. That is truly the setting where we think canakinumab has the best chance of working," Narasimhan told journalists. "It is a high-risk study, nonetheless we're looking forward to getting that readout towards the end of 2022."

Novartis has pulled the plug on a couple of oncology projects. The Phase I asset Lu-PSMA-R2 for prostate cancer, a radioligand therapy acquired with the purchase of Advanced Accelerator Applications, has been discontinued due to prioritization, while a Phase II combinational trial looking at the anti-PD-1 drug spartalizumab in melanoma has also been ended. (Also see "*Novartis Hits Spartalizumab Phase III Setback In Melanoma*" - Scrip, 24 Aug, 2020.)

Novartis Hopes For Canakinumab In Lung Cancer Nosedive

By Kevin Grogan

25 Oct 2021

After deciding to examine canakinumab's potential in lung cancer on the back of the CANTOS cardiovascular trial, Novartis designed a major late-stage program in oncology for the interleukin-1 beta inhibitor. The second of those CANOPY trials has just come crashing down.

Read the full article here