Bristol-Myers Squibb CEO Discusses Q3 2013 Results - Earnings Call Transcript

Bristol-Myers Squibb (NYSE:BMY)

Q3 2013 Earnings Conference Call

October 23, 2013, 10:00 a.m. ET

Executives

John Elicker – Senior Vice President, Public Affairs and Investor Relations

Lamberto Andreotti – Chief Executive Officer

Charles Bancroft – Executive Vice President and Chief Financial Officer

Giovanni Caforio, M.D. – President, U.S. Pharmaceuticals

Béatrice Cazala – Executive Vice President, Commercial Operations

Francis Cuss – Executive Vice President and Chief Scientific Officer

Analysts

Seamus Fernandez - Leerink Swann

Mark Schoenebaum – ISI Group

Jami Rubin - Goldman Sachs

Christopher Schott – JPMorgan

Alex Arfaei - BMO Capital Markets

Tim Anderson – Sanford C. Bernstein

Andrew Baum – Citi

Steve Scala – Cowen & Company

Vamil Divan - Credit Suisse

Gregg Gilbert – Bank of America Merrill Lynch

Operator

Good day. Welcome to today's third quarter earnings 2013 earnings release conference call. This call is being

and public affairs. Please go ahead, Mr. Elicker.

John Elicker

Thanks, operator, and good morning everybody. Thanks for joining us to review our Q3 results. With me this morning with prepared remarks are Lamberto Andreotti, our chief executive officer, Charlie Bancroft, our chief financial officer. And this morning, also with prepared remarks, will be Francis Cuss, our chief scientific officer. And then joining for Q&A are our two commercial leads, Executive Vice President Béatrice Cazala, and the president of U.S. operations, Giovanni Caforio.

Before I turn it over to Lamberto, I just want to cover the Safe Harbor language. As you know, during the call, we'll make statements about the company's future plans and prospects that constitute forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the company's SEC filings.

These forward-looking statements represent our estimates as of today and should not be relied upon as representing our estimates as of any subsequent date. We specifically disclaim any obligation to update forward-looking statements, even if our estimates change.

We will also discuss non-GAAP financial measures adjusted to exclude certain specified items. Reconciliations of these non-GAAP financial measures to the most comparable GAAP measures are available at our website, bms.com.

Lamberto?

Lamberto Andreotti

Thank you, John. Good morning everyone. This is an important time for Bristol-Myers Squibb. The third quarter marked our return to growth with respect to both sales and earnings, as we made our way through the Plavix loss of exclusivity. And that, combined with our continued pipeline progress positions us well for the future.

Let me elaborate on these points. With respect to sales, not only was our growth strong, up 9%, but also it was diversified, cutting across our portfolio. We drove double-digit growth in Yervoy, Orencia, Sprycel, and Onglyza, and the contribution to the top line results from Eliquis and Bydureon started to become meaningful.

This is important. It demonstrates the breadth and quality of our diversified portfolio. Yervoy remains the cornerstone of our growth in our oncology platform. I'm excited, in fact I'm very excited, by the data presented at the European Cancer Congress in September, as it confirms long term survival with Yervoy in metastatic melanoma and reinforced the overall value of this product.

Last quarter, Yervoy continued to deliver growth, most notably in Europe and our international markets. Yervoy results in the U.S. were also positive, notwithstanding the impact of a significant number of new clinical trials targeting melanoma patients with other agents. In Europe, the CHMP recently recommended that Yervoy be approved as first-line therapy in advanced melanoma.

With respect to Eliquis, I'm encouraged. We are still very far from the sales levels these products can achieve,

to execute against our strategy to clearly define the differentiated and unique profile of Eliquis.

In other countries, we will increase our peer-to-peer medical education activities, and in the U.S. you may have seen that we began our DTC advertising campaign in September for Eliquis in atrial fibrillation.

We are also working to expand our label, as we have filed an NDA for VTE prevention in the U.S., which is already an approved indication in Europe, and we plan to file our application in VTE treatment this year.

With respect to our diabetes portfolio, we continue to find our way through this very competitive space. In the third quarter, Onglyza sales grew 19% year over year, and within our exenatide franchise, Bydureon sales showed encouraging gains.

And with Dapagliflozin, we are looking forward to the FDA Advisory Committee meeting in December and the PDUFA date in January.

Now, let me make a couple of comments about our pipeline. With respect to hepatitis C, we believe that we have an interesting opportunity and we are looking forward to AASLD conference next month, when we will present new data on the Phase III trials pre-trial of our all-oral dual regimen, and we are still on track for its important submission in Japan this year.

And with respect to immuno-oncology, 2013 has been a year of exciting data for our immuno-oncology platform. Data we have presented so far this year spoke to the very real possibility of paradigm-changing treatments for a range of cancers, and next week we will present additional immuno-oncology data at the World Conference on Lung.

Now, because there is much happening related to our work in immune-oncology, I've asked Francis to spend a few minutes this morning to walk you through our thinking with respect to this increasingly important area for us. Francis?

Francis Cuss

Thank you, Lamberto, and good morning everyone. As you well know, we've been focused on expanding our efforts in immune-oncology as an area where we see a potential paradigm shift in the treatment of patients with certain cancers. We believe that immuno-oncology has the potential to be transformational in the treatment of patients suffering from various types of cancer.

The durability of response and long term survival in some patients are quite unlike anything we've seen in the past, as demonstrated by the long term survival data for Yervoy recently presented at the European Cancer Congress. Additionally, early data suggests that the immunotherapeutic approach has the potential to provide a benefit not only in tumors traditionally considered immunogenic, but also in other tumor types that have not typically been thought to be immune mediated.

As the field continues to evolve and expand, we believe that there may be roles for monotherapy, combination therapy, and biomarker-directed therapy, and we are therefore building our development programs to prepare for all possibilities.

Certainly, the approaches are likely to vary by tumor type as well as by line of therapy. Through our experience with Yervoy and broad programs with Nivolumab, we have a unique understanding in the field which gives us confidence that we are well-positioned to find the ultimate way to utilize these innovative therapies.

As you know, we've made a very large commitment to immuno-oncology. Currently, for Nivolumab alone, we have over 25 ongoing clinical trials across more than eight tumor types. We continue to explore Yervoy monotherapy in additional tumor types such as prostate and lung, as well as in combination with Nivolumab.

In addition, we have a broad portfolio of exploratory immunotherapeutic agents with varying immune mechanisms of action that allows us to explore multiple combinations. Today I'd like to provide a brief update on the status of our major programs. Let me start with lung cancer.

As a follow up to the data we presented at ASCO in June, we will be presenting updated two-year survival data from the lung cohort of prior treated patients in the Nivolumab monotherapy study known as 003 at the World Conference on Lung Cancer at the end of October.

Next up will be data from the Phase I combination study of Nivolumab with Yervoy in non-small cell lung cancer, which we expect to have in house by the end of the year. This study will provide important information on the feasibility of combinations in this tumor type and potentially inform our plans for Phase III trials starting in the first half of 2014.

Following that, we expect to have data in the first part of 2014 from our Phase II study in third line squamous non-small cell lung cancer. If the results of the study demonstrate a favorable benefit risk profile, we plan to discuss the data with the FDA and other health authorities.

Finally, we have two ongoing Phase III trials in second line non-small cell lung cancer, one in squamous and one in non-squamous, with both studies collecting information on PD-L1 tumor expression. We expect to have data from these studies later in 2014.

In melanoma, we have a broad program ongoing with trials covering all lines of therapy, which includes monotherapy as well as combination of Nivolumab and Yervoy. In previously untreated patients, both monotherapy and combination Phase III trials are underway, and a Nivolumab monotherapy Phase III trial is ongoing in advanced patients who have progressed post-Yervoy.

In renal cell cancer, our most advanced trial is focused on focused on metastatic disease, comparing Nivolumab with everolimus. Early trials are exploring the combination of Nivolumab and Yervoy in first line renal cell cancer, and we expect the data in house by the end of this year. And also, we expect early data on the potential role of biomarkers in this tumor type.

In all these three tumor types, we remain committed establishing the benefit-risk profile of Nivolumab as quickly as possible, and are closely collaborating with health authorities.

Now, regarding public data presentations, after the lung data at the World Conference on Lung Cancer, we expect the next set of presentations to be at ASCO in 2014, which may include data on the Phase I combination

which is ongoing.

In addition to the programs for Nivolumab that I highlighted earlier, we're also exploring its use in additional solid tumor types, including pancreatic, gastric, small cell lung cancer and triple negative breast cancer, as well as hematological malignancies.

So, in closing, I think you can see that we have a significant commitment to advancing the field of immuno-oncology through a broad program that is science-driven, diversified, and well resourced. We believe that this commitment, together with our expertise and experience, puts us in an excellent position in this tremendously exciting area.

So now I'd like to turn it back to you, Lamberto.

Lamberto Andreotti
Thanks, Francis. Well, clearly we see immuno-oncology as an important and exciting opportunity for us, one in which we will continue investing heavily, dedicating even more resources, time, people, and money, not only in R&D but also commercially, as we prepare for potential launches.

We are also committing the right commercial resources to our key growth drivers, most notably Eliquis, diabetes, and hepatitis C. These products and these therapeutic areas are our future, and my management team and I are determined to set the stage for long term, sustainable growth while at the same time driving short term performance.

Now, with that, I will turn the floor over to Charlie to talk through some of our key numbers. Charlie?

Charles Bancroft
Thank you, Lamberto. Net sales were $4.1 billion in the quarter. We also had solid sales performance across our entire portfolio, especially for Yervoy, Sprycel, Orencia, and Bydureon. Let me provide a few highlights.

Yervoy sales increased 33% year over year to $238 million. Yervoy continued to show strong performance in Europe. We recently received a positive opinion from the CHMP for first line use of Yervoy and hope to have marketing authorization later this year. This is an important addition to our label in Europe and will allow a broader set of patients to potentially benefit earlier in their treatment.

In the U.S., Yervoy sales softened somewhat from the second quarter. As Lamberto mentioned, we have seen an impact from a significant increase in new clinical trials targeting melanoma. Patient enrollment in metastatic melanoma trials has more than doubled since the beginning of the year, with some of that increase coming from our own clinical trials with Nivolumab.

While these clinical trials have affected the commercial opportunity at several large academic institutions, we continue to focus on growing Yervoy in the community setting, which represents approximately 60% of our U.S. sales. Recent weekly sales trends are encouraging.

We believe having the first line indication in Europe, along with the survival data presented at the European

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