Company Name: AstraZeneca
Company Ticker: AZN LN
Date: 2018-05-18
Event Description: Q1 2018 Earnings Call

Market Cap: 66384.3788713
Current PX: 5241
YTD Change($): 136
YTD Change(%): 0.0

Bloomberg Estimates - EPS
Current Quarter: 0.785
Current Year: 3.45
Bloomberg Estimates - Sales
Current Quarter: 5391.889
Current Year: 22602.19

Q1 2018 Earnings Call

Company Participants

- David Fredrickson, Executive VP & Global Head Oncology Business Unit
- Marc Dunoyer, Executive Director & CFO
- Mark Mallon, EVP
- Pascal Soriot, Executive Director & CEO
- Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Other Participants

- Alex Arfaei, Pharmaceuticals Analyst
- Andrew Simon Baum, Global Head of Healthcare Research and MD
- Matthew Weston, MD and Co
- Richard J. Parkes, Director
- Sachin Jain, MD
- Simon P. Baker, Analyst
- Timothy Minton Anderson, Senior Analyst

Presentation

Operator

Welcome, ladies and gentlemen, to AstraZeneca's Q1 Results Analyst Conference Call.

Before I hand over the call to Pascal Soriot of AstraZeneca, I'd like to read the safe harbor statement.

The company intends to utilize the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Participants on this call may make forward-looking statements with respect to the operations and financial performance of AstraZeneca. By their very nature, forward-looking statements involve risk and uncertainty. And results may differ materially from those expressed or implied by these forward-looking statements. The company undertakes no obligation to update forward-looking statements. (Operator Instructions)

Now I'll hand you over to AstraZeneca, where the call is about to start.

Pascal Soriot, Executive Director & CEO

Hello, everyone. It's Pascal Soriot here, CEO of AstraZeneca. Welcome to our First Quarter results conference call and webcast for investors and analysts. We're here in London on a very beautiful day for the Annual General Meeting this afternoon. We have people on the phone and on the webcast. The presentation is available to you on astrazeneca.com, as always, for you to download.

Please turn to Slide 2. This is the safe harbor.

Please turn to Slide 3. We plan to spend about 30 minutes around the presentation today and then leave plenty of time for Q&A. (Operator Instructions) There is also an option to ask questions online as part of the webcast. As we would like to provide everyone with an opportunity to ask questions, please limit yourselves to one question each in the first run. Thank you very much in advance.

So today, I'm joined, as always, by Dave Fredrickson, Executive Vice President for the Oncology business unit; Mark Mallon, our EVP for Global Products and Portfolio Strategy, Medical Affairs and Corporate Affairs; Marc Dunoyer, our CFO; and Sean Bohen, our EVP for Global Medicines Development and our Chief Medical Officer.

Please turn to Slide 4. This is the agenda where we will cover all the key aspects of our First Quarter announcement today.

And if you want to turn to Slide 5, please. So now we are on to the highlights. We'll be making comments on our financial performance using core reporting metrics and at constant exchange rates, CER, which are both non-GAAP measures. All numbers will refer to million U.S. dollars and growth rates would be at CER unless we otherwise state.

So our product sales overall declined by 2%, as anticipated. The strong performance by the newer medicine, up 66% and by China, was offset by the tail of the loss of exclusivity on Crestor in the EU and in Japan that started impacting us last year and also about 2% negative impact from divestments overall.

In general, there are many moving parts in the sales line, as you digest, the loss of exclusivity masking underlying performance. As implied by my comments, the Second Quarter may be quite a bit like the First Quarter. And product sales growth will, therefore, be weighted towards the second half of the year as (comparisons ease.) Total revenue declined by 9%, reflecting lower initial externalization revenue while the pipeline of opportunities remain intact.

The key here is that we're very excited by the new medicines and their launch trajectories. This newer medicines collectively deliver more than $0.4 billion in additional sales versus Q1 '17. And they grew by 66%. Oncology was up by 33%, driven by Lynparza, Tagrisso and Imfinzi that are all performing very well. And we'll come back to that later. New CVRM, Cardiovascular, Renal and Metabolism, was up by 8%; and Brilinta is growing by 24%; Farxiga by 39%. So both doing very well.

Respiratory was 6% lower, essentially impacted by Symbicort's competitive environment and also by a supply delay in China for -- that impacted Pulmicort and its result in the meantime.

So on the other hand, we had a very strong start for Fasenra in respiratory and in -- that we launched it in the U.S. in asthma and we also launched in Germany and are rolling out to other markets.

Finally, the Emerging Markets continued to grow at high single digit, driven by China that grew by 22% and, for the first time, past the $1 billion mark in the quarter. A fantastic result in China for Q1.

Core EPS was at $0.48, reflecting the Crestor impact in the EU and Japan. But also the investment we have to make in launching all these products; we have 6 launches underway. And also the investment in China as we continue to fuel our growth there. At the same time, we'll remain committed to our productivity improvements and our total core operating expenses were down by 1%. Our guidance remains unchanged. And it's supported by the performance of the newer medicines in the quarter.

And finally, a few days ago, we took further steps in creating a more focused, pharma-sized biopharmaceutical company with the divestment of Seroquel in some international markets. We remain fully committed to our strategy and the increasing focus on our 3 main therapy areas of oncology, CVRM and Respiratory. However, without being too specific, there are still some medicines left in AstraZeneca that may fit and perform a lot better in another company. And we will keep you updated during the year on new agreement.

With this, let's look at the pipeline of potential new medicines. If you turn to Slide 6, we continue to make progress with our pipeline that is aiding the transformation of AstraZeneca. Lynparza tablets received a broad EU label in ovarian cancer and breast cancer. The breast cancer submission was accepted also in the EU. Tagrisso started to receive the first approvals in the first-line setting. We got the first approval first in Brazil, which really was a great success by our Brazilian team, followed by the U.S. In the EU, we received a positive opinion. And we are awaiting approval later this quarter. Getting Tagrisso's unprecedented benefit to patients in the first-line setting remains a top priority for all of us.

This priority also goes for Imfinzi, which was approved and launched in the U.S., also with significant patient benefit in the earlier unresectable Stage III setting of lung cancer. EU and Japan regulatory decisions are expected in the second half of the year. The combination of Imfinzi and tremelimumab did not show any significant benefit on the primary endpoints in the third-line PD-L1 low or negative lung cancer setting in the ARCTIC trial. However, while the Imfinzi monotherapy sub-study A was not powered for statistical significance, Imfinzi showed a clinically meaningful reduction in the risk of death compared to chemotherapy in this setting.

Last, in Oncology, moxetumomab's first biologic license application was filed, accepted and received Priority Review in the U.S. for third-line hairy cell leukemia. And selumetinib received Orphan Drug Designation.

In CVRM, Forxiga was accepted for review in the EU in type 1 diabetes as an add-on to insulin. And Lokelma received the first regulatory approval.

And finally, in Respiratory, Fasenra didn't meet the primary endpoint in the first of 2 trials in COPD. We're now awaiting the second trial for firm conclusion on the utility of Fasenra in the disease.

Please turn to Slide 7. We'll now review our important sales performance as we return AstraZeneca to growth in 2018. First of all, on the total product sales, the First Quarter was down by 2%, as I said before. And it was impacted by the tail of the loss of exclusivity for Crestor in the EU and Japan. We lost Crestor in the U.S. last year, as you know. Still impacting in the U.S. this year. But mostly Japan and the EU. We expect this impact to continue in the Second Quarter. But then it should ease in the second half of the year. And so the comparison then would become easier. It also goes for the impact from divestments, in particular, the divestment of the local anesthetics business last year.

As is visible, after the First Quarter, we have many opportunities to support our return to sales growth in 2018, including the newer medicines that are important to the future of AstraZeneca: Lynparza, Tagrisso, Imfinzi, Brilinta, Forxiga and Fasenra. The major offset is the tail of the impact from the loss of exclusivity for Crestor, as you know. We, therefore, can reconfirm our guidance of low single-digit growth in product sales in 2018.

If you turn to Slide 8, as we mentioned last quarter, we focus sales reporting on the main therapy areas going forward. And this is how they performed during the First Quarter. Oncology was above $1 billion per quarter -- for the quarter. And it grew by 33%. This is probably the fastest-growing diversified oncology business of any company. And we're now making up 1/4 of our total business in Oncology. New CVRM, excluding Crestor, is made up of Brilinta in diabetes and also soon Lokelma and in the future roxadustat. And together, they grew by 8% to almost $1 billion (first) quarter.

Respiratory was down 6%, reduced by the competitive environment for Symbicort and the timing of U.S. government orders. But we are encouraged by the launch of Fasenra, which taken significant market share already. Other medicines were down by 19%, reflecting the loss of exclusivity for Crestor in EU and Japan and the divestment. This line will remain in some decline as we focus all our efforts on the main therapy areas.

Emerging Markets continued their strong performance with 8% growth. And China, in particular, grew by 22% to a record of more than $1 billion in the quarter. It's really pleasing to see China performing so well. And I would like to offer my sincere thank you to the China team who're making this possible and the benefit they bring to patients in China.

Please turn to Slide 9. As I said before, newer medicines delivered an extra $0.4 billion in the First Quarter. And they grew by 66%. The -- Tagrisso there was the main contributor, followed by Forxiga, Imfinzi, Lynparza and Brilinta. We will continue to monitor how our newer medicines are doing, both looking back at sales but also looking forward at leading indicators.

Please turn to Slide 10. Looking at a few specific examples of launches. And we selected those 3 leading indicators from our U.S. business and how it is returning to growth. In Oncology, the new-patient starts for Imfinzi show a very exciting trend and are accelerating after the formal U.S. approval in unresectable Stage 3 cancer. Physicians are excited to bring the important benefit of Imfinzi to their patients with an earlier nonmetastatic stage of lung cancer. And our team there is doing a brilliant job.

In CVRM, Bydureon's new injection device, BCise, has helped Bydureon increase its new-to-brand prescriptions. Actually, for the first time in several years, we're pleased to now offer U.S. patients a convenient device to treat type 2 diabetes. Also a great job by our Diabetes team.

And finally, in Respiratory, another great result, really, by our team there. Fasenra is off to a very encouraging start and already gaining market share of new patients compared to other available medicine targeting the IL-5 pathway in severe eosinophilic asthma. In fact, in new prescriptions, since we are the leader in the IL-5 class already.

In summary, we are very encouraged by this positive impact made by the newer medicines in the 3 main TAs as they underpin the guidance of returning to growth in product sales in 2018.

I will now hand over to Dave and Mark to cover other important aspects of our product sales. So if you want to turn to Slide 11. And they will now take us through the Oncology TA.

David Fredrickson, Executive VP & Global Head Oncology Business Unit

Great. Thank you. So much, Pascal. And I'm really pleased here to be here to update all of you on the performance of our new generation of medicines. I'll start first with Oncology. And then I'll hand it over to Mark Mallon for a summary of CVRM, Respiratory and Emerging Markets.

If we could turn, please, to Page 12. We are really pleased to announce that total Oncology grew by 33% quarter-over-quarter. And now represents 1/4 of total product sales for AstraZeneca. We've now delivered 4 of the 6 New Oncology medicines that we set out an ambition to deliver by 2020. And we really see that all 4 of these medicines are contributing to the growth of $300 million in additional sales versus the First Quarter of 2017. We see continued growth from Lynparza and Tagrisso. And very importantly, Imfinzi truly has realized an inflection point as we've launched in the United States with the approval of the stage 3 unresectable PACIFIC indication. We continue to see encouraging uptake in Calquence as prepare for the larger CLL indication, with data starting to come next year. And it is worth highlighting, though I won't speak about it anymore in the presentation, that other Oncology medicines are still growing at 1%, which is mainly driven by the label extensions for Faslodex.

If we could turn please to Slide 13. Now turning to Lynparza. We've now seen 3 quarters of strong growth. And for the quarter, we grew by 100% over the same quarter of last year, with total global sales of now $119 million. This is with strong growth across all regions: U.S., Europe and Emerging Markets, as we continue to roll out the broader label in ovarian cancer tablets and the breast indication in the U.S. U.S. sales were $66 million in the quarter, up 144%, which was driven by an increase in demand from the all-comers label in the second-line ovarian cancer as well as from the breast cancer indication. As you would expect, we see the majority of use in ovarian cancer. But there is emerging use in breast. Together, they make up about 80% to 85% of the total sales in Lynparza. Lynparza was the leading medicine in the PARP inhibitor class in the U.S. as measured by total prescription volumes.

European sales were robust at $42 million, up 44% versus the prior year. And this reflects our effort and emphasis on driving testing rates and it's boosted by additional launches across several markets that hadn't yet come online. We are really pleased to have the broader EU ovarian label now included too as of last week in Europe.

In markets outside the U.S., in Europe, Lynparza has just this month launched in Japan. And so while not in the First Quarter numbers, early signs of launch are promising. And we'll have more to update on that in our next call.

Finally, the Merck alliance continues to progress nicely. And we look forward to an exciting year of delivery of what we believe is the leading PARP inhibitor.

Please turn to Slide 14. Now we'll talk about our medicines within the lung cancer portfolio and beginning with Tagrisso. Tagrisso had strong performance again across all markets with 89% growth in the quarter, resulting in $338 million in sales. And this has been primarily driven by second-line demand and higher testing rates. Tagrisso is now the largest product within our Oncology portfolio. U.S. and EU exhibited strong growth, with sales of $147 million and $69 million, respectively. And this is really as a result of being established as the clear standard of care in second line at

this point. Japan did experience a softer quarter, mainly due to the mandatory expiration of a testing program, which resulted in testing rates going down and also in a decline in bolus patients in the late line. But we look for this to turn around with the near-term catalyst of the frontline FLAURA approval, which is expected later this year. We're excited that we can announce the frontline FLAURA was approved in Brazil and then in the U.S., which we believe will further drive sales as we already have seen some contribution of this to sales not only from our launch but also following the NCCN compendium listing from last year.

We continue to build on the EGFR lung cancer opportunity, where we believe that we are truly leaders in the science and in the space. We've kicked off a trial in locally advanced patients, called LAURA, for Tagrisso, which will address unmet need in earlier disease as we hope to truly bend the survival curve for patients with this terrible disease.

If we could turn now to Slide 15. We really have had an encouraging start to Imfinzi. It was approved for the U.S. with the PACIFIC indication for unresectable stage 3 non-small cell lung on the 19th of February. This has resulted in a true inflection point for Imfinzi with sales now of $62 million in the First Quarter and, really, the overwhelming majority of these coming from the lung cancer indication. As you saw from a slide that Pascal showed in February when we launched, we had about 3,500 patient infusions per month and you can see that we've now doubled in the most recent month to 7,000 patient infusions per month, really showing that the underlying patient demand is the driver of these sales. Initial feedback from the launch has been very positive from physicians and from patients alike, though lots of educational effort remains, as we need to ensure that we continue to drive treatment rates post-CRT and bring awareness into the setting, where previously there hadn't been any alternatives available.

Please turn to Slide 16. Lastly, I'd like to talk about our Hematology franchise. And I'd like to highlight the good start that we've made with the launch of Calquence. We hope that this is the first of a much broader platform that we look to build upon in years to come, including our potential fifth new oncology medicine, moxetumomab, which Pascal mentioned briefly and Pascal will talk about -- and Sean will talk about it a bit more. Calquence continues to perform well, with sales of $8 million in the First Quarter in the fast-to-market, second-line, relapsed recurrent mantle cell lymphoma indication. We now see about 1/4 of new patients starting on Calquence within this setting. And we look forward to the chronic lymphocytic leukemia data readouts, which we expect to start from 2019.

As mentioned, moxetumomab is our first potential antibody-drug conjugate. And we look forward to the regulatory decision in the Third Quarter for this niche but high-unmet-need disease of hairy cell leukemia.

With this, I turn it over to Mark.

Mark Mallon, EVP

Thanks, Dave. Now moving to new CVRM which, as Pascal mentioned, is defined as our medicines in Cardiovascular, Renal and Metabolic diseases.

Sales were up by 8% despite the intense competition, with First Quarter sales at $900 million. Farxiga and Brilinta continued to remain strong with double-digit growth across all regions. Brilinta sales of $293 million with 24% growth, driven by the U.S. at 32% and Emerging Markets at 20%. And Farxiga delivered sales of $299 million in the quarter, with 39% growth. And Farxiga maintained volume market share leadership globally with a 41% share. Farxiga growth of 32% in the U.S. exceeded SGLT2 class growth. However, we are seeing some slowdown in the SGLT2 class growth. And we're looking forward to DECLARE results in the second half of this year.

Ex U.S., where we have 58% of our global sales for Farxiga, we've been seeing encouraging performances. For example, in Brazil, Farxiga is the #1 innovative oral diabetes medicine.

Turning back to the U.S. In the fast-growing GLP-1 market, our autoinjector, Bydureon BCise, continues to perform well, as Pascal mentioned. Importantly, roughly half the patients are new GLP-1 patients going onto Bydureon BCise. And 1/3 have been switched from the Bydureon Pen.

Please turn to Slide 18. Now turning to Respiratory. As Pascal mentioned, sales continue to see challenges in the quarter with an overall sales decline of 6%. For Symbicort, product sales were down by 12%, with the U.S. particularly adversely affected in part due to phasing of government purchases. We anticipate the U.S. price compression to remain with moderate easing throughout the year. Globally, Symbicort volume is holding steady, with some growth in the U.S. in the -- in demand. Overall, sales growth in Emerging Markets was held back by a delay in releasing Pulmicort supply in China, which we have addressed. And Symbicort delivered growth of 10% in the quarter.

Please turn to Slide 19. Fasenra, as you saw, is off to a strong start. And we're very happy with the initial launch, which has been consistent with our expectations given its highly competitive clinical profile. The success has also been supported by our strong prelaunch preparation, which was enabled by a dedicated team staffed with highly experienced respiratory and biologic sales colleagues who were able to hit the ground running. We also put in place an industry-leading support program to help patients and physicians gain reimbursement for Fasenra as quickly as possible for the patients that need it. Fasenra reported sales of $21 million in the quarter, resulting mainly from the U.S. launch at the end of last year. We look forward to Japan and the other markets that are launching as we speak coming onboard the next quarter.

Please turn to Slide 20. Emerging Markets continue to track in line with our long-term performance target with 8% sales growth in the quarter. China delivered strong performance with 22% growth and a record of over $1 billion of sales in the quarter for the first time. China benefited from the addition of more medicines to the National Reimbursement Drug List last year and the launch of Tagrisso. Outside China, we saw the impact from divestments and general economic conditions, specifically in Russia where the business was impacted by lower health care spend.

Finally, there was strong performance across our core therapeutic areas in Emerging Markets, with Oncology up 36%; Respiratory, up 5%; and new CVRM, up 30%. And although we missed the China National Reimbursement Drug List timing update for Forxiga, we've added already a number of provincial reimbursement list and very pleased with the launch so far in China for Forxiga.

And with this, I'll hand it over to Marc.

Marc Dunoyer, Executive Director & CFO

Thank you, Mark. And hello, everyone. I'm going to spend the next few minutes taking you through our financial performance in the First Quarter of the year as well as our unchanged guidance.

Please turn to Slide 22. As usual, I will begin with the reported P&L before turning to the core numbers. As Pascal mentioned earlier, product sales declined by 2%, impacted by the reduced sales of Crestor in Europe and Japan. The effect of the divestment of medicine in prior periods, such as anesthetics, also reduced our product sales by about 2%. But as you heard earlier, we delivered especially promising performances in China and right across our Oncology medicine. As implied by my comments. And while we do not guide on a quarterly basis, the Second Quarter may look a bit like the First Quarter and product sales growth will, therefore, be weighted towards the second half of the year as comparisons ease. The lower level of initial externalization revenue this year meant that total externalization revenue declined by 67% in the quarter despite the inclusion of a $70 million milestone received from Merck for the approval in breast cancer for Lynparza. The performance over top line was in line with our expectation. And so I'm keeping my guidance for product sales unchanged.

Please turn to Slide 23. Turning now to the core P&L. Our gross margin ratio for the year fell, as expected, by 4percentage points to 78.8%, driven primarily by the positive impact of manufacturing variances in Quarter One 2017 and the inclusion of the profit share with Merck. The decline in the sales of Crestor also had an impact.

Total core operating expenses declined by 1%, the result of our continued focus on core discipline. Core R&D costs were reduced by 12%. We did, however, see an uplift in core SG&A costs in the quarter, driven by some specific factors, which I will talk about in a moment.

Core other operating income declined by 64%, a result of the timing of our divestment this year. The core tax was 18%, in line with indication of our full year core tax range of 16% to 20%.

Please turn to Slide 24. Looking at the externalization revenue in more detail, there was a reduced level of initial externalization revenue, which led to the overall decline year-on-year. By nature, there will never be a smooth and even pattern of agreements (and receipt,) but I want to be clear that we expect a significant level of externalization revenue this year, including from Merck. We remain committed to focusing on appropriate cash-generating and value-accretive agreements given the productivity of our pipeline. We're also committed to the continued management of our portfolio divestment and to increasing the focus on our 3 main therapy area over time.

Please turn to Slide 25. We made further progress on our core discipline in the quarter. As I mentioned earlier, total core operating expenses fell by 1% despite the investment in the launches. Core R&D costs fell by 12%. Despite maintaining a high level of activity level, we saw the benefit of productivity initiative and efficiencies. And there was also a support from the Merck collaboration cost-sharing agreement. The investment in our business remain one of our capital allocation priorities and, we are enjoying the benefit of more targeted investment in our pipeline. I continue to anticipate a stable to low single-digit decline in core R&D this year. Core SG&A costs increased by 6%, reflecting investment in the launches and in China. It is worth noting that Quarter One 2017 saw one of the lowest level of core SG&A spend in many years. And core SG&A declined sequentially from Quarter Four 2017 into Quarter One 2018. I currently anticipate a further significant year-on-year uplift in core SG&A cost in the Second Quarter. But I want to reiterate our expectation of a low to mid-single-digit percentage increase in core SG&A cost over the full year.

Please turn to Slide 26. And I'd like to conclude with a reiteration of our 2018 guidance, which is on product sales and core EPS. We anticipate low single-digit percentage growth in product sales for 2018 at constant exchange rate. Growth is significantly weighted towards the second half. And we expect the pressures on product sales seen in Quarter One to continue in quarter 2. This pattern reflect -- particularly reflects the first half impact of generic competition to Crestor in Europe and Japan. I continue to anticipate the sum of external revenue and other operating income to be less than that in 2017. We also anticipate a core EPS of $3.30 to $3.50 at constant exchange rates. With the financial performance in line with our expectation as well as success of our pipeline in newer medicine, I'm confident in our ability to deliver against what are unchanged and consistent capital allocation priorities.

With that, I will hand over to Sean.

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Thank you, Marc. I would now like to run through the late-stage pipeline events since the last results announcement and the highlights of recent data presentations at medical meetings. And as usual, I will finish with a look at our upcoming news flow.

Please turn to Slide 28. We delivered more good progress in the quarter in Oncology. Lynparza received EU approval for a broad second-line ovarian cancer indication with a tablet formulation, while we also received submission acceptance for breast cancer. Tagrisso received the important U.S. approval for first-line EGFR mutated non-small cell lung cancer and also received submission acceptance in the EU.

In Hematology, moxetumomab submission was accepted by the FDA and granted Priority Review for an intended indication in third-line hairy cell leukemia. On the data front, we announced that the ARCTIC trial of Imfinzi plus tremelimumab in third-line non-small cell lung cancer did not meet the primary endpoints of PFS and OS in patients with PD-L1 low or negative tumors. But as discussed in the announcement, the Imfinzi monotherapy sub-study A, while it was not powered for statistical significance, showed a clinically meaningful production in the risk of death compared to chemotherapy.

Continuing on data, we presented the ovarian cancer cohort from the MEDIOLA trial and Lynparza plus Imfinzi was demonstrated to be well tolerated. Response rate was greater than 70% within the entire cohort. And for patients with one prior line of therapy, the response rate was 77%.

Following the data presentation, we announced plans for a Phase III trial of Lynparza plus Imfinzi in ovarian cancer. There are more details for you in today's results announcement.

At AACR and ELCC in April, we also shared overall survival data for Lynparza in breast cancer and data from both our ATR and ATM inhibitors in Phase II. In IO combo, the second-line cohort of study 006 in non-small cell lung cancer, was presented with study 10 in bladder cancer. We also presented data for Tagrisso from the FLAURA Phase III trial looking at patients after progression, which continued to emphasize Tagrisso's impressive efficacy and safety.

Please turn to Slide 29. Staying on Oncology and continuing our momentum, at ASCO this year, we will be sharing key data across our Oncology portfolio. We are pleased to have more than 90 abstracts, 14 oral presentations and 7 Best of ASCO designations. From our DNA Damage Response portfolio, we will share Phase II results from our study 8 trial in prostate cancer, where we combine Lynparza and abiraterone. Further on Lynparza combinations, we will share results of Lynparza combined with vistusertib in ovarian cancer and triple negative breast cancer. In addition, we will also present data for other potential new medicines focused on DNA Damage Response, including data from a Phase II trial of our highly selective oral AKT inhibitor, capivasertib, in metastatic triple negative breast cancer.

In immuno-oncology, we will have additional Imfinzi monotherapy data, including safety data, from the PACIFIC trial in unresectable stage III non-small cell lung cancer and updated Phase II results in third-line non-small cell lung cancer from the ATLANTIC trial. Further, we will show Imfinzi monotherapy data from study 1108, this time in gastrointestinal cancers and small cell lung cancer. As for Imfinzi combination with tremelimumab, we will have Phase I data in non-small cell lung cancer from study 006 in Cohort C, which are IO pretreated patients; and other data in gastrointestinal cancers and small cell lung cancer from their dedicated combo trials; and then in mesothelioma, which is in combination with chemotherapy.

In Hematology, Calquence results from Phase I/II trial in WaldenstrÃ¶m macroglobulinemia will be presented, as will data from moxetumomab pasudotox in relapsed or refractory hairy cell leukemia. There are other data points as well, including selumetinib in neurofibromatosis type 1, an orphan disease. And we hope many of you can join us at our ASCO investor event on Monday, June 4, in Chicago.

Please turn to Slide 30. In CVRM, we received EU approval for Lokelma. The combination of Bydureon plus insulin in Type 2 diabetes also received U.S. FDA approval. For Forxiga, the EU accepted our regulatory submission for the treatment in type 1 diabetes, a potential new use of the medicine.

Staying on Farxiga, CVD-REAL 2 was presented and was consistent with CVD-REAL 1, which was presented last year. In CVD-REAL 2, more than 400,000 patients across 500 countries -- across 5 countries were treated with SGLT2 inhibitors. The data was analyzed with 75% of these patients receiving Farxiga. The analysis demonstrated that the treatment with an SGLT2 inhibitor was associated with a lower risk of all-cause death, lower risk of hospitalization for heart failure, lower risk of myocardial infraction and lower risk of stroke. As a reminder, the DECLARE Phase III cardiovascular outcomes trial is on track for top line data in the second half. And the primary endpoints include hospitalization for heart failure.

Please turn to Slide 31. I want to conclude by highlighting some of the upcoming news flow. For Lynparza, we soon anticipate first-line data in ovarian cancer with potential regulatory submission in the second half. Following the U.S. approval in breast cancer, we expect a regulatory decision in Japan during the second half and a regulatory decision in the EU next year. For Tagrisso, in the first-line setting, we anticipate regulatory decisions in EU this quarter and Japan in the second half.

Moving to immuno-oncology. We anticipate EU and Japan regulatory decisions for the PACIFIC trial in unresectable stage III non-small cell lung cancer in the second half. Further in lung cancer, we expect data readout from MYSTIC in the second half, with NEPTUNE now coming in 2019.

In head and neck cancer, we expect data from the KESTREL first-line and the EAGLE second-line trial in the second half. Our first-line bladder cancer trial, DANUBE, will have a data readout in 2019.

In CVRM, the Phase III DECLARE trial will be available later this year. We anticipate a regulatory submission for Bydureon's autoinjector in the EU in the second half. And as communicated by our partner, FibroGen, we now anticipate data for roxadustat in the second half and regulatory submission to follow in 2019.

In Respiratory, our regulatory submission for PT010 in COPD is expected in the second half. Staying in COPD, we announced that Fasenra did not meet the primary endpoint in the first COPD trial, GALATHEA. But we expect the second trial, TERRANOVA, to report this quarter, which will further inform our plan. Finally, we expect data from anifrolumab in lupus in the second half of the year.

With this, thank you to everyone for your continued support. And thanks to all of the hard-working colleagues in AstraZeneca, who come to work every day, to make this happen.

Please turn to Slide 32. I will now hand back to Pascal for closing comments.

Pascal Soriot, Executive Director & CEO

Thank you, Sean. Please turn to Slide 33. Now let me summarize before we end. We are really pleased with the ongoing launches and the performance of our newer medicines during the First Quarter, as they underpin the guidance of growth in product sales in 2018. Our financials are on track, with our performance being weighted towards the second half of the year. And with product sales leading the way. Total revenue reflected lower initial externalization revenue with an unchanged pipeline of opportunities. We remain focused on productivity, as shown by a 1% decline in total core operating expenses, while we also continue to invest for growth in our products -- in our new products and in China. The commercial execution is very strong with $400 million of additional sales versus the First Quarter of 2017, 66% growth from the newer medicines that are key to the future in AstraZeneca. And our oncology platform, in particular, is starting to take really good shape. The pipeline continue to deliver important news flow. Based on the First Quarter performance and the encouraging trend on product sales, we reconfirm our 2018 guidance today. So we now go to the Q&A. (Operator Instructions) We'll also take written questions from the webcast. Can I please remind everybody to limit questions to one to be fair to all of our callers. Thanks in advance for your help with this. And for us, I'll take the first question from the conference call.

Questions And Answers

Pascal Soriot, Executive Director & CEO

So we have a question here from Simon Baker at Exane. Simon, go ahead.

Simon P. Baker, Analyst

One for Sean, please, if I may. We can see from the press release this morning the expanding and evolving PARP IO combination trials that you're conducting. But I was just wondering how much further there is to expand that. I'm thinking areas like colorectal, where there's been some interesting work published this year on the potential applicability of PARP in that indication. And also, therefore, potentially to add IO in there. And I was also wondering about the scope for IO PARP combinations where the IO is KEYTRUDA instead of Imfinzi through the joint venture.

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Okay. So let me -- sort of 2 questions there. One is the expansion of I'm going to call Lynparza IO. So Lynparza Imfinzi or Imfinzi, plus treme. So when we shared our ovarian cancer data, we also shared that we have -- we are initiating a trial called DUO-O, which is looking at that combination specifically in ovarian cancer. Then we are looking at other data sets to see where we might expand beyond that. With regard to data in other indications, that

MEDIOLA trial does have multiple expansion cohorts. We haven't shared them all yet. But we will use data from those expansion cohorts to help inform what additional confirmatory trials we might do in other expanding indications. With regard to the scope of the KEYTRUDA Lynparza combination, we actually don't share information with Merck -- between Merck and AstraZeneca on what we're doing with Lynparza in the context of IO combination. So that's really not an AstraZeneca question, it's a question that should be addressed to Merck about their activities.

Pascal Soriot, Executive Director & CEO

Thank you, Sean. There's a question on the webcast that we'll read aloud from Vincent Meunier at Morgan Stanley. So he's trying to understand the potential of Tagrisso initiative that were before you. And the question is, are there countries where the prevalence of the EGFR mutations is higher than other countries? What about Japan? And also, in China, what is the breakdown of volumes, sales that's in China between the private channel and, I guess, (all other) channels?

David Fredrickson, Executive VP & Global Head Oncology Business Unit

So thank you for the question. So yes, there are countries where the prevalence is higher. And in Asian countries, it tends to be the highest around the globe. Prevalence rates in the U.S. and in European countries for EGFR mutation is around 15%. And in Asian countries, we see it around 30%, even as much as 35%. Japan, China, Korea, this would all be the case for those countries as you look through that. On the second question, in terms of the breakdown of volumes and sales in China, the majority of the sales in China that we're seeing right now are coming from the private channels. There is a few examples of provinces that have included reimbursement. But really, again, the demand that we're seeing in China and the growth is coming from the private sector.

Pascal Soriot, Executive Director & CEO

Thank you, Dave. Then there's a question from Tim Anderson at Bernstein. Tim, go ahead.

Timothy Minton Anderson, Senior Analyst

Emerging Markets and China are a big part of your business. And in China, your proportion of total sales coming from that region is much higher than peers. I usually thought of Emerging Markets exposure as a good thing. But you could argue it's the other way around because profit levels are less. Markets like China, you may get volatility tied to price cuts. So with Astra, investors generally look for margin expansion over time. I'm wondering if your growing emerging market presence could actually end up holding you back in this regard. So can you talk about this? And quite simply, can you just disclose to us what the operating margin is in Emerging Markets? And again, I'll slip a second question. And a very short one, can you say whether Astra was approached by Trump's attorney, Michael Cohen, at any point? And if you were, can you confirm that you did not do business with him?

Pascal Soriot, Executive Director & CEO

Let me just cover the second question, Tim. Then Mark Mallon, you might want to cover the China question. The second is very simple and straightforward, Tim. We were not approached, didn't talk to Michael Cohen. So we're totally out of this discussion. China, Mark?

Mark Mallon, EVP

So we definitely see China as a positive and to have such a strong position in there. And we see continued growth and future potential. Of course, every country around the globe is wrestling with health care costs. And as we've seen in the last week in the U.S., there is risks around pricing actions. And I don't think China represents particularly more or less risk than any other countries. In fact, you might argue that China is sending signals to be even more committed to innovative medicines in the way they've been supporting changes in the China FDA, adopting global standards and recently adding a number of products to the NRDL. So we're really confident in the future prospects in China. Of course, in overall Emerging Markets, you will have disruptions because the economies are not as mature. And so you'll have ups and downs. But it's really a strong portfolio for us. In terms of operating margin, we've talked about this before. The business, Emerging Markets, is a profitable business. Particularly in China, we have a very -- there's very much profitable growth and, in the margin, I think we've talked about as being a bit below what we see in Europe. But absolutely an attractive business for us.

Pascal Soriot, Executive Director & CEO

Yes, Mark. I think with China, Tim, we have to sort of combine 3 things. Well first of all, I mean, the population is, of course, as we all know, very large. But the economy is maturing to focus now on innovation and has very strong momentum. So that will bring additional purchasing power. The private label, the private insurance label, the government is starting to fund pharmaceuticals in a broader way. We got reimbursement last year from additional 5 medicines, including some that are newer medicines. The -- as Mark said, you've got opening to -- the government is now looking at regulations to open the way to fast-track approvals, et cetera. And the final thing, I think, which is really something we cannot say enough, is we have a tremendous team. I think we have an incredibly talented team of individuals in China. And we have the scale. And when you get the right people, the right team and you have the scale, then you create a momentum that is really quite formidable. And that's exactly where we are today. Now as Mark said, I mean, of course, China will be exposed to price pressures as the market grows. But nothing different from what we experienced in Europe or in the U.S.

So we move to Matt Weston at CrÃ©dit Suisse. Matt, go ahead.

Matthew Weston, MD and Co

Pascal, my question's on the cost base really. Higher SG&A has been one of the key discussion points this morning with investors. Mark mentioned the low base effects. But also the guidance range of low; to mid-single-digit growth is a large window. So can you just give us some of the drivers of that range? Is it competitors potentially reacting in respiratory that you may need to react to? It doesn't look like it could be upcoming launches because LOKELMA in the U.S. is the one only that's controversial. So is it the outcome of DECLARE or roxa? Some help there would be very useful.

Pascal Soriot, Executive Director & CEO

Yes. I mean, let me try. And Mark Mallon and Marc Dunoyer, you could also help me. But just in terms of the new launches, I mean, we've talked about quite a number of new launches, Tagrisso, et cetera, et cetera, for sure. Now in the second half, I think you've got to think of roxa and LOKELMA. But they're like more in the prelaunch mode, if you will. Including in the U.S., LOKELMA, after we get approval, we're going to spend a fair amount of time seeking access. You cannot launch these days in the U.S. without an appropriate access. Otherwise, you struggle. So we're going to take some time to focus on access. So those 2 medicines will be in the prelaunch mode. And I think DECLARE is the other one. But much less requirements than the first half, of course. And the other 2, Marc, if you want to add?

Marc Dunoyer, Executive Director & CFO

No. I think we are -- just one word. We are obviously launching 8 -- in total 8 new medicine line extensions or new formulation. And obviously, we are -- this is very -- an important timing for the final trajectory. So we are closely monitoring the performance of these brands as they are being launched. And this is why we try to allocate as much resources as we can dedicate to ensure the final success on those brands.

Pascal Soriot, Executive Director & CEO

Maybe one last point that I should have added actually because the comments I made were -- and I guess, Matt, your point related to the U.S.. But we also have to think that as we progress, we start launching in Europe as well. So Europe is a little bit behind, as always, because you need to get approval. But also reimbursements. So the launch of Imfinzi will come later in Europe. So then you have sort of a ramp-up.

Mark Mallon, EVP

I'll just add one (point) again is China. And China, to your point, we have great scope and scale. But we still have so much more to penetrate. And so we have to continuously -- we are continuously expanding into new hospitals and customers and even cities. And also, we're doing multiple new launches in China. So it's not just the established portfolio. We've got many launches occurring at the same time. So that's also part of the picture.

Pascal Soriot, Executive Director & CEO

So as you can hear, we are -- yes. Go ahead, Matt.

Matthew Weston, MD and Co

If I could just ask one quick follow-up. So I have no question regarding the increased spending in SG&A because, clearly, you're in full launch mode. I understand that. Everything that everybody seems to have referred to in your answer is events that are known to you or very highly likely to happen, with the exception of, really, DECLARE and roxa. My question was really about, what about the 5percentage point range embraced in the guidance? How should we think about the need for you to flex the investments? What are the triggers for you to go to the high end of the range or the low end of the range, given that it seems that you should already know and have fully planned for what you need to do?

Marc Dunoyer, Executive Director & CFO

Matt, first of all, we provide guidance on product sales and EPS. So these are the 2 variables we obviously closely look at. There are obviously several lines in the P&L between product sales and EPS. But you need to remember, we have provided guidance on these 2. And we will be doing our best to meet or exceed this guidance for the year.

Pascal Soriot, Executive Director & CEO

So we committed to the guidance. And in fact, the variation, Matt, is really based on what opportunities we see. I mean, we see a new opportunity somewhere that could drive additional sales and profit. And we flex at that point. But essentially, as Marc said, we'll stick to the guidance. So we can move maybe -- maybe the last point I was going to make earlier is that you can see we're in a -- and as you mentioned yourself, we are at a maximum pressure point this year in terms of the launches. And moving forward, clearly, we expect that to improve substantially.

So Mark Purcell at Redburn has a webcast written question. And are we ready to (release) about the gross margin? And the question is, you have a reduction in the core gross margin to 78.8%. Can you help us understand what proportion of this reduction came? And that will be for you, Marc. It came from, first, positive manufacturing variances in Q1 '17; two, the MSD collaboration; three, patent expiries; and four, buildout of biologic manufacturing capacity, which is yet to be utilized. Can you help us understand where you are with the biologic manufacturing capacity buildout, how much capacity you will have when this is completed. And when utilization will kick in and help expand on the gross margin again?

Marc Dunoyer, Executive Director & CFO

So the 5 point reduction is obviously a reduction from Quarter One 2017, Quarter One 2018. And roughly, the 4 factors that have been proposed are more or less equivalent to explain the difference. So the buildout of the biologic manufacturing, the lower absorption, because we are early in the launch, this is about 1/4 of it. Mix effect on products, such as Crestor, this is another 1/4 of this variance. The impact of the profit sharing with MSD, again, another 1/4. And the better situation that we had in 2017 quarter 1, because we had positive variances, procurement, credit and such things, this is another 1/4. So you have these 4 -- these are the 4 factors that explain the difference between the first half or the First Quarter of 2017 and 2018. If you now compare the second half of 2017 and the First Quarter of 2018, you will see that the gross margin ratio are very similar. So -- and I indicated, several times, in the course of '17, that the first half was not going to be a good prediction for the second half of '17. But I also said that second half will be quite helpful to guide for 2018. So my recommendation is for you to look at the second half of '17. And also to look at the first half of -- sorry, the First Quarter of '18. These numbers should help you anticipate the gross margin for the full year 2018.

Pascal Soriot, Executive Director & CEO

Thank you, Marc. As far as the capacity build, we are kind of almost done with this. We're completing our filling plant in Sweden. But in terms of manufacturing product substance, we're done. And then we will start using that capacity over time.

So we now have a question from Andrew Baum at Citi. Andrew, go ahead.

Andrew Simon Baum, Global Head of Healthcare Research and MD

So I suspect Astra has received the request for information from the HSS following the drug pricing announced. Could you give us a sense of how much follow-through to expect in relation to this announcement, particularly the conversations about removing the protective class? And I'm thinking of categories such as PARP. And maybe just then a quick one for Sean. Could you just outline your plans for your AKT inhibitor 5363? Is there any possibility of filing for an accelerated approval despite the caveat of the data, given there is an OS signal and PFS? Or should we assume that Phase III is going to be the development path of the product?

Pascal Soriot, Executive Director & CEO

2 great questions. I must say the line was breaking up. The second question is clear, for sure. And the first one, hopefully, Mark, you got that one okay?

Mark Mallon, EVP

Yes. What I heard, Andrew. And if I'm off track, please correct me. But you asked about, did we get a request to provide information as part of the drug pricing plans that the administration are working on. And how much do we expect that to come through the system. I think as you know and we all know, I mean, there were a lot of, I think, over 50 potential actions highlighted in the administration's plan, some requiring correctional actions, some (that they can move on.) So it's hard for us to predict how much of this is going to impact ideas like moving classes of reimbursement around between Part B, Part D, other approaches that they may take. It's just too early for us to make a prediction on that. What I can say is that we're happy to be talking with the administration around what we could do to around innovative contracting. And thinking about outcome-based contracts, we have quite a bit of success in that in the commercial area. We've got over 30 contracts now across the whole portfolio that are outcome-based contracts. And so we're looking forward to actually engaging in the very near future to see what we might be able to do within the government sector. So...

Pascal Soriot, Executive Director & CEO

Yes, yes. So I mean, we've been very successful with some of the outcome-based pricing contracts we've implemented. And if we could expand on those as part of a broader policy that the administration would want to put in place, I think it would really be very welcomed by us and, I'm sure, by many other companies. Sean, do you want to cover the AKT question?

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Sure, sure. Thank you for the question, Andrew. So the question relates to the Phase II data that (you've seen the abstract. And) we'll present it in more detail at the ASCO meeting. Capivasertib, our AKT inhibitor in triple negative breast cancer, metastatic breast cancer, we think the data's encouraging. We think it's pretty strong indication of activity of the AKT pathway in triple negative breast cancer, which is a significant unmet need. It's very poor prognosis, subset of breast cancer. With regard to accelerated approval, it would really be speculative at this point to get into whether that might be an acceptable pathway. So what we do is we take the data. We make, in any case, a decision as to do we want to or need to confirm it with a Phase III trial. Then I think with regard to whether there's some more accelerated path, it's really a discussion with regulatory agencies as to whether they see the data as supporting that. The one thing you mentioned was survival. And we are encouraged by the consistency across endpoints.

Pascal Soriot, Executive Director & CEO

Thank you, Sean. As you can see, more to come on this one. But certainly very exciting early data with this new agent coming out of Cambridge research team. So really, really good new development. We'll extend the (TC) by about 10 minutes so that we give everybody a chance to ask a question.

And the next one on the list here is Sachin Jain at Bank of America. Sachin, go ahead.

Sachin Jain, MD

On Lynparza, similar to the prior question, the likelier combo is associated with a PFS benefit. So any thoughts of filing that study? J&J have talked about filing a (inaudible) strategy on response rate data. And if that study isn't fileable, just what are your plans for the combination given the PROfound Phase III study is currently a monotherapy study?

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Okay. So I think -- Sachin, let me clarify. Your -- in this case, you're referring specifically the Study 8 data in prostate cancer when you say in combination for...

Sachin Jain, MD

Correct.

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Okay. Okay. Great. Well I think the -- I mean, I think the answer is not dissimilar to the answer I gave for Andrew's question with regard to capivasertib. Again, we do -- we find that data encouraging from Study 8. Again, the question is really whether there's a regulatory pathway to bring that forward. And that's a discussion with regulators in order to decide whether or not we are going to do that. Then obviously, it's a discussion as well with regard to Lynparza abiraterone in a Phase III setting to confirm. Then PROfound, we do have ongoing. But recall, PROfound's -- it's a different setting in terms of later-stage disease, also single agent in that particular case. And then as well very heavily dependent on biomarker hypothesis looking at genes in the DNA Damage Response portfolio and mutation in those genes as inclusion criteria.

Pascal Soriot, Executive Director & CEO

Excellent. So there's a question on the webcast by Sam Fazeli at Bloomberg. And the question is, can you explain the reasoning behind starting PACIFIC 2? So sort of the PACIFIC program, Sean, do you want to cover that?

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Yes, sure. Yes. The rationale behind PACIFIC 2 really has to do with the fact that while concurrent administration of chemotherapy and radiation therapy are the well-established standard of care in the United States and Europe, there are many parts of the world where concurrent isn't the standard of care. And a lot of that has to do with the challenges of coordinating that radiation therapy and chemotherapy. So PACIFIC 2 allows the testing of the maintenance hypothesis that occurred in -- I'm sorry, that's China PACIFIC I'm talking about. That's the maintenance-type hypothesis following sequential. PACIFIC 2 has a different question, which is that in PACIFIC, we did sequential administration of Imfinzi after the completion of chemoradiotherapy. PACIFIC 2 asked the question, what happens if you start everything at the same time? And so that'll be a concurrent chemo radiation therapy, IO therapy going forward.

Pascal Soriot, Executive Director & CEO

Thank you, Sean. I think we have -- maybe we'll take another 2. So we have one question here, Alex Arfaei at BMO. Alex, you want to go ahead?

Alex Arfaei, Pharmaceuticals Analyst

Great. Well just looking at your operating margin here, I fully appreciate the headwinds you're facing with the patent expirations and the investments, the maximum pressure points on launches, et cetera. But as you step back and look at your business, how realistic is it for investors to expect that once things normalize, you should have an operating margin that's more in line with your European and U.S. peers? And when should we expect that? And a follow-up, if I may, on Imfinzi. Are you just seeing -- are you seeing adoption of unresectable Stage III patients as well? And when do you expect PD-1 (composition) in Stage 3?

Pascal Soriot, Executive Director & CEO

Okay. So the second question will be -- Dave, you could take. And in the first question is about margins. When you look at our peers, you really have to be careful who you look at because some companies have such a very focused business around, say, specialty care. And sometimes, it's even beyond that specialty care U.S. with a little bit of European presence. So the margins, of course, reflect a little bit the business shape. So you've got to take -- compare ourselves to some of our European peers or even U.S. peers, that have the same kind of mixture of specialty care and primary care. So having said this, as a context, it is clear that we intend to see our margins improve. We're at the maximum pressure point this year. We've got so many launches, as you can see, at a time when we have a business that, to some extent, is small relative to the size of our pipeline in a number of launches. But typically, you have a legacy business that is helping you and is large or at least relative to the pipeline is large. It's not our case. So we are really going through maximum pressure point. But from 2019 onwards, suddenly, our goal and our expectation is to see the operating margin improve as the business ramp up. So yes, we have another question, PD-1. Sorry, Dave.

David Fredrickson, Executive VP & Global Head Oncology Business Unit

Yes. So on the first question of the uptake that we've been seeing with Imfinzi in Stage III unresectable, as I mentioned earlier, the lion's share, in fact, the overwhelming majority of our sales in the First Quarter, came from that population. As you saw earlier in one of the slides from Pascal, you can see the demand increasing with Imfinzi within this population. We had an estimated 3,500 monthly infusions in February. You can see that it's more than doubled or almost doubled, excuse me, into what Pascal showed was an April number of 7,000 two months later. So we really are encouraged by very good growth in the underlying demand. And the growth is demand-based as opposed to inventory or stocking-based that we've seen. From a competition perspective, we are the first. And we believe, based upon our scanning, that we have an 18 to 24-month lead on other Phase IIIs. Again, those are all event-driven and have to do with the recruiting paces, et cetera. So it's difficult to predict. But those are our estimates for how much (we had).

Pascal Soriot, Executive Director & CEO

Sorry, did you want to...

Sean Bohen, Chief Medical Officer & EVP of Global Medicines Development

Yes. I believe if I heard you right, Alex, there was a question as well around resectable disease. And obviously, that's not the indication. So that's not something we track. I just want to point out that we do have an ADJUVANT study ongoing, which studies that question very specifically, Stage Ib through IIa non-small cell lung cancer post-surgical therapy. They do better than unresectable patients. But they don't do very well. And so the first data for that is anticipated in 2020. And again, as Dave said, we believe we're quite a bit ahead in that setting as well.

David Fredrickson, Executive VP & Global Head Oncology Business Unit

Yes. And just so that I'm clear. And almost -- I mean, 100% of our use is in the unresectable population post-CRT. And in the U.S., that represents about 80% of Stage III in terms of the unresectable population.

Pascal Soriot, Executive Director & CEO

So we'll take the Marietta's question on the webcast at Primavenue. And she's asking a question about Farxiga and in China and saying, "I didn't realize you could get provincial reimbursement without being on the NRDL." And also, "Is there a chance to get on the NRDL through negotiations that are outside the official window for reviews and

additions?" Mark, do you want to cover this?

Mark Mallon, EVP

Yes. So thanks, Marietta. It's a great question. So yes, you can. We've done this in the past with other products. In fact, I should say getting on the NRDL doesn't guarantee you that you get listed on the province level. This is why Pascal -- one of the reasons Pascal keeps highlighting the importance about the quality of our people and the scale of our business is because we have dedicated market access teams in all of the major provinces. And that's what's leading to the success in Farxiga and the speed of which we can take advantage of NRDL listings. This isn't going to replace the NRDL. We can't -- it's still -- the NRDL is critical because we won't get all provinces through this process. And the question about, would we negotiate in advance of the NRDL, if there was an opportunity to make a difference for patients. And we thought we could agree with the government on what's the right value proposition, then, certainly, we'd look at this. I think China's committed to accelerating the regularity of updating the NRDL list. So hopefully, that won't be something that we need to do. But actually, as an example, roxa was the case where we did this. And it's been a very good thing for patients and a very good thing for our business. So I think this is just highlighting the strength -- another part of the strength of our team in China. And they should be congratulated for the great work they're doing here.

Pascal Soriot, Executive Director & CEO

Not only you can get provincial reimbursement, you can sometimes get city reimbursement. So there are many, many different sources of access in China.

And the last question, Richard Parkes of Deutsche Bank. And we'll finish with Richard's question. Go ahead, Richard.

Richard J. Parkes, Director

Great. So again, it's on Imfinzi and the Stage III in resectable lung cancer setting. So if you look at the IMS weekly sales, it looks like you're annualizing now well north of $400 million. I'm just wondering if you could give us any kind of sense of where you are in terms of penetration of that unresectable setting in the U.S.. And maybe whether that strong launch would make you reevaluate your floor in terms of north of $1 billion? And just in addition to that, you talked about, in the slides, need for physician education to continue to drive that growth. I just wondered if you could elaborate on where you think you need to improve understanding of the drug's potential utility.

Pascal Soriot, Executive Director & CEO

Thanks very much, Richard. I appreciate the question. That will help us in our discussions with Dave actually. And the forecast, you're absolutely right, the last weekly data points are pretty good. And Dave, do you want to cover that one?

David Fredrickson, Executive VP & Global Head Oncology Business Unit

Yes. Absolutely. So I think the first place, just to comment on in terms of where we see the penetration. And I want to ground it just in the CRT behavior. So again, about 80% of Stage III patients are unresectable. Of those, half gets CRT. And that is not something that has really changed too dramatically in terms of the number of CRT patients post that are unable to get unresected. So one of our big educational opportunities that we do see, of course, is to grow the number of Stage III patients that are getting CRT and to have discussions about that. Now among those who get CRT and who were able to not progress, which is the majority of them, we have seen that about half of those now are getting treatment with Imfinzi in the post-CRT setting. And so that's really the area that we've been focused in on. We think

that that's growing quite nicely. But the educational opportunities are around, really, educating on an option that exists post-CRT that really creates a chance to, in a curative setting, keep patients in Stage III. And this is one of the major areas that we are focused in on because, as I've mentioned before, physicians have truly not had any other options available to them up until this point. So we're really trying to build the Stage III market and show that there's now an opportunity to raise the bar with respect to curative intent within this setting.

Pascal Soriot, Executive Director & CEO

Thanks, Dave. And as you can imagine, of course, we're also launching in Japan and the Rest of the World, Europe, et cetera, later this year and into early next year. So there's a lot more to come as it relates to Imfinzi. But give me a chance before I conclude. Give me a chance to thank Dave and the oncology team in particular in the U.S. with the fantastic Imfinzi launch. And also the Tagrisso team and the Lynparza. And everybody in the oncology team in the U.S. and around the world doing a tremendous job. The Fasenra team, you saw -- Mark Mallon showed you the market share and absolutely incredible ramp-up in terms of new prescription share. So we are really on a good track with this one, too. And the cardiovascular diabetes team is suddenly driving growth across the CVMD portfolio that is suddenly very exciting, too.

So let me quickly conclude. First of all, thank you for all your support and interest. And just conclude by saying we -- as I said, we are really very happy and pleased with the result of our launches so far and the performance of our newer medicines during Q1. Our financials are on track. Clearly, we are at the maximum pressure point in terms of the cost of launching those products. But we are on track with what we expected. We certainly reconfirm our guidance for the year, both in terms of costs. But also our EPS. At the end of the day, the very exciting part and very important part to keep in mind is the growth we see in China, the fact that the commercial execution around the world is very strong with about $400 million of additional sales in Q1, 66% growth from these newer medicines that are key to our future. And based on all this strong performance as well as the continued delivery of important news flow, we reconfirm our product sales for the year and our guidance. So again, thank you for your interest. And a good weekend to everybody.