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Tom Curry/FPL/Corp/SB_PLC
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Subject
As requested - Deutsche Bank Report Overview

As requested, the document below was prepared by the US advair marketing team to address issues that may be raised as a result of the recent Deutsche Report that referenced "an abrupt slowdown in US sales of Advair".

Tom C

----- Forwarded by Tom Curry/FPL/Corp/SB_PLC on 20-Jul-2004 05:26 PM -----

Ted T Geiger/PharmUS/GSK
20-Jul-2004 17:23

To
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Subject
Deutsche Bank Report Overview

Lafmin - final copy of the assessment of the DB report.

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Deutsche Bank Report Commentary

The following comments from the Advair Marketing Team on the Advair Report from Deutsche Bank provide clarification and context for specific comments made regarding Advair and the asthma and COPD markets.

Advair Performance

Advair growth rates for 2004 are in line (slightly behind) corporate expectations (23% vs. 20%). Net sales growth at the end of 2003 % was somewhat higher than underlying TRx growth during the same time period; 3Q2003 (57% vs. 37%) and 4Q2003 (51% and 30%). These differences can be explained somewhat by a price increase earlier in 2003, and a worse than expected along with an earlier than expected influenza season that resulted in artificial inflation of the new prescription volume during that time period. Many of the patients treated during this period received a single Advair prescription since they were not asthma or COPD sufferers. Any inventory build at the wholesaler level has burned off, as inventory levels are at an all time low of Advair (Approx. 11 days in 2Q04)

Comparing Advair to other blockbuster products suggests that our growth rate is in line with other products exhibiting blockbuster performance (see below).

	Year 2	Year 3	Year 4
Lipitor	193%	50%	30%
Celebrex	39%	6%	-7%
Vioxx	125%	4%	-20%
ADVAIR	97%	33%	23%

The Deutsche Bank report projects monthly MAT growth to be 12% by end-June. Early Alert Rx reports have projected a 16.2% June TRx growth rate for Advair, with MAT growth of 26.2%.

Deutsche Bank is pessimistic about the opportunity to impact the Advair growth rate in 2004, despite changes in resource allocation and promotional focus. Advair currently has 27% share of asthma/COPD controller prescriptions, which implies that nearly ¾ of these prescriptions are in competitive products. We are confident that the changes that we have made to the selling POA and the promotional message will drive growth in Q3 and Q4. The changes include:

- Refocusing selling efforts towards asthma, both childhood and adult
- With the childhood asthma indication, we are poised to take advantage of the highly seasonal pediatric asthma market
- Focus on earlier use of Advair, specifically in patients who have uncontrolled asthma but are typically thought of as 'mild' by primary care physicians

Asthma Market penetration peaking

The Deutsche Bank report presents Advair penetration of the asthma market using the NIH Guideline severity classification. "Strict adherence to the US guidelines would imply that Advair usage should be confined to patients with moderate and severe persistent asthma". The report also points out that asthma is managed via a step care approach, which limits Advair use to a more severe population. Finally, Deutsche Bank concludes that Advair already has 40% of use in the overall asthma population.

To our knowledge, there is no reliable quantitative source of data that provides Advair share by severity classification, and we do not support the analysis. Additionally, the most recent patient level data suggests that Advair has approximately 32% share of asthma patients (SDI, May '04). Considering that each percentage point in patient share represents \$75MM to Advair, significant opportunity remains if we only achieve the estimate of 40% currently asserted by Deutsche Bank.

The report also suggests that step-care in asthma is appropriate given the guidelines. The asthma guidelines do not support step-care; the guidelines recommend therapy based upon physician assessment of patient symptom severity. Primary care physicians typically do not take the time to objectively assess patient symptoms; hence, they adopt a step-care approach to treatment, relying on the patient to return with complaints if therapy is not sufficient to relieve symptoms. If PCPs assessed their patients, they would prescribe Advair to more of their population. GSK strategy is to provide a simple, quick and accurate assessment tool (Asthma Control Test: ACT) to drive proper patient assessment, which will result in more patients on Advair.

We agree with Deutsche Bank that there is significant opportunity in the 'mild population' if that patient population is defined as those using short acting beta agonists (SABA) alone to manage their asthma. 75% of SABA users fill 3 or more units of albuterol per year, while 25% fill 10 units, clearly indicating they should be prescribed maintenance medications. (Source: SDI, May 2004) Given the step-care approach to treatment, many of these patients treated with SABA would benefit from earlier treatment with Advair.

Deutsche Bank points out that GSK will use the results of the step-down study and the misdiagnosis of asthma data to drive Advair growth. Additionally, we will

use two studies which enrolled patients symptomatic on albuterol, a population typically viewed as 'mild' to fuel growth. One study compared Advair to Singulair, and the second compared Advair to Flovent. In all studies Advair helped patients achieve more symptom free days and dramatically reduced SABA use. Both of these studies have been replicated and published in peer reviewed journals.

GOAL could provide the next impetus to growth

We agree that the GOAL study results represent an excellent opportunity for Advair, and have been used in promotional activities by the EU since early 2004. The US plans are to incorporate the study results into speaker training meetings to make certain that they are briefed and able to handle questions from other physicians regarding the data. Using the data in direct promotional activities by the sales force has been problematic due to FDA comments on the study regarding the limited population in the US (10%) and the lack of validation of the total-control endpoint.

Pediatric Opportunity

Deutsche bank suggests that the 4-11 population represents about 13% of the pediatric opportunity, with Advair market share within the pediatrician prescribers is only 15%, half of the share in other specialties. They also suggest that GSK has been slow to take advantage of this new indication.

The report highlights Singulair's position in childhood asthma, and the lack of Advair data in the 4-11 population as preventing strong penetration for the brand.

For clarity, the pediatric indication was received on April 23rd, with final preparation of materials in May and a launch meeting the first week of June. Additionally, pediatricians account for only about ½ of the prescriptions written for childhood asthma; the balance coming from other prescribers, primarily PCPs and allergists, who also treat adults. We believe the 4-11 indication provides an opportunity for us to expand Advair business within these adult treating physicians.

COPD Commentary

Use of Advair in COPD is high, and is growing faster than use of anti-cholinergics:

- SDI data indicates that Advair is used in 34% of all treated COPD patients, and this share has increased by over 5 points in last year. In the same time period, anti-cholinergics grew only 1 share point in % of treated patients.
- Verispan uses for Advair in COPD have accelerated in first four months of '04 with strong gains among both pulmonologists and PCPs

- IMS data also show a strong 1Q for Advair in COPD, with share increases for Advair in treatment consultations and market revenue. Also, IMS showed that COPD is growing as a % of the overall use of Advair.

Opportunity to continue growing in COPD market is significant:

- Patients with COPD suffer from poor lung function, frequent symptoms and are high utilizers of healthcare
- Use of multiple products is high (45% of treated patients are on 2+ maintenance products). In fact, nearly half of all treated patients are on an ICS, often with bronchodilator therapy (beta-agonist and/or anti-cholinergic). The majority of patients in the clinical development program for Spiriva were on ICS.
- 66% of 5M treated COPD patients are not yet on Advair
- 65% of patients using anti-cholinergics are not yet on Advair
- There are 15M untreated and mis/un-diagnosed patients with COPD

Spiriva launch into the COPD market is significant:

- Spiriva uptake from launch is much less than that for Advair
- Initial uptake of Spiriva has not appeared to effect Advair Diskus TRx volume
- Although patients may eventually be treated with both Spiriva and Advair, Advair will compete successfully with Spiriva for early use in COPD:
 - Only Advair Diskus 250/50 offers both an anti-inflammatory and a long-acting bronchodilator that work together to help patients breathe easier
 - Only Advair Diskus 250/50 is superior to a long-acting bronchodilator (salmeterol) in improving lung function and helping patients with moderate or severe COPD breathe easier, due to the contribution of FP
 - Advair Diskus is indicated for maintenance treatment of asthma, as well as COPD associated with chronic bronchitis. ATS guidelines state that it can sometimes be difficult to distinguish between the two conditions. About half of patients who are treated for COPD also have an asthma diagnosis.
 - Advair Diskus is convenient and ready to use

Advair vs. Combivent studies:

- Donahue et al now published in Treatments in Respiratory Medicine
- Make et al (second study) presented at ATS
- Representatives are unable to promote these data affirmatively. A Medical Information letter is sent in response to unsolicited questions.

Advair will succeed by effectively managing these opportunities and challenges in the COPD market, while also pursuing growth opportunities in the larger asthma market.

Other Corrections

Page 6: Figure 3

Advair growth as a percentage of GSK growth is artificially inflated by including the 255% growth rate in Advair for 2003. Using the 2004 – 2008 time period suggests that Advair is important, but continues to decline as a percentage of GSK growth to 34% in '08, with an average of 37% (vs. 52% as reported by DB) for the 5-year period.