From: "JScott@P4Healthcare.com" <reply-3055@elabs7.com>
Subject: **PROOF: Tykerb® (lapatinib)**
Date: March 27, 2007 9:17:38 AM EDT
To: cbacher@p4healthcare.com
Reply-To: reply-3055@elabs7.com

P4 Healthcare
The Healthcare Information Exchange

Dear Colleague,

I would like to make you aware of a recently approved treatment option for patients with advanced or metastatic HER2-positive breast cancer who have received prior anthracycline, taxane, and trastuzumab.

Please take a moment to review this correspondence from Dr. Paolo Paoletti, Senior Vice President, Oncology Medicine Development Center, GlaxoSmithKline announcing the recent FDA approval of Tykerb® (lapatinib).

His letter contains the necessary links for the full prescribing information for this new product.

This communication was funded by GlaxoSmithKline.

Sincerely,

Jeffrey A. Scott, MD
P4 Healthcare
jscott@p4healthcare.com
www.caring4cancer.com
www.p4healthcare.com

Dear Doctor,

GlaxoSmithKline is pleased to announce the availability of Tykerb® (lapatinib).

TYKERB is indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and

trastuzumab.[1]

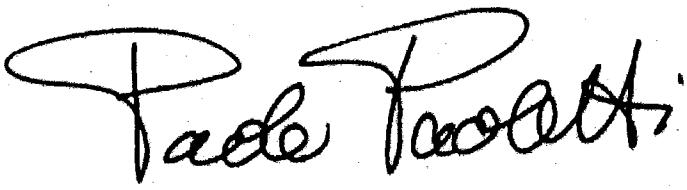
TYKERB gives you and your patients a new way to suppress HER2 receptors by working intracellularly to inhibit the tyrosine kinase components of EGFR and HER2 receptors, commonly associated with breast cancer cell proliferation and tumor growth.[1]

This approval was based on the pivotal Phase III trial of 399 patients which showed that the median time to disease progression as assessed by independent reviewers was 27.1 weeks on the combination of TYKERB and capecitabine versus 18.6 weeks on capecitabine alone in women with advanced or metastatic HER2 (ErbB2) positive breast cancer whose disease had progressed following treatment with trastuzumab and other cancer therapies. The hazard ratio of 0.57 (95% CI: 0.43, 0.77, p = 0.00013) represents a 43 percent reduction in the risk of progression for the patients on the combination arm.[1] Differences between treatment groups based on unblinded investigator assessments were smaller but continued to be clinically and statistically significant.

Adverse events (AEs) leading to discontinuation were similar in the TYKERB-capecitabine combination arm (16 percent) versus capecitabine alone (13 percent). Most commonly reported AEs in the TYKERB-capecitabine combination arm included diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue. Left ventricular ejection fraction (LVEF), a measure of the strength of the heart's pumping capacity, was monitored during the study. Among 198 patients who received the TYKERB-capecitabine combination treatment, three experienced an asymptomatic (grade 2) decrease in LVEF and one experienced a symptomatic (grade 3) decrease in LVEF.

To support patient access, GlaxoSmithKline has established a single source for information and support called the Tykerb® *CARES* program. Through this comprehensive program, knowledgeable consultants are available to offer support for treatment adherence by providing product-related information to patients before they start their therapy. These consultants are also available to answer any questions doctors and patient advocates may have about TYKERB. Additionally, Tykerb® *CARES* reimbursement counselors will help patients understand their insurance coverage and, if appropriate, assist in identifying alternative financial support. More information regarding Tykerb® *CARES* can be found by calling 1-866-4-TYKERB (89-5372). Program hours are Monday to Friday, 8:30 AM to 8:00 PM ET.

Sincerely,



Paolo Paoletti, MD
Senior Vice President
Oncology Medicine Development Center
GlaxoSmithKline

Please click here to to read full U.S. Prescribing Information for Tykerb® (lapatinib).

Reference: 1. TYKERB [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007.

GlaxoSmithKline Oncology

Tykerb® CARES (lapatinib)

Please click here to review P4 Healthcare's Privacy Policy. Please click here to review P4 Healthcare'sTerms and Conditions.

P4 Healthcare LLC
6031 University Blvd.
Suite 235
Ellicott City, MD 21043

To unsubscribe, click here

From: "JScott@P4Healthcare.com" <reply-3055@elabs7.com>
Subject: **PROOF: [TEXT] Tykerb® (lapatinib)**
Date: March 27, 2007 9:17:38 AM EDT
To: cbacher@p4healthcare.com
Reply-To: reply-3055@elabs7.com

P4 Healthcare LLC

Dear Colleague,

I would like to make you aware of a recently approved treatment option for patients with advancedor metastatic HER2-positive breast cancer who have received prior anthracycline, taxane, and trastuzumab.

Please take a moment to review this correspondence from Dr. Paolo Paoletti, Senior Vice President, Oncology Medicine Development Center, GlaxoSmithKline announcing the recent FDA approval of Tykerb® (lapatinib).

His letter contains the necessary links for the full prescribing information for this new product.

This communication was funded by GlaxoSmithKline.

Sincerely,

Jeffrey A. Scott, MD
P4 Healthcare
jscott@p4healthcare.com
www.caring4cancer.com
www.p4healthcare.com

Dear Doctor,

GlaxoSmithKline is pleased to announce the availability of Tykerb® (lapatinib).

TYKERB is indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.[1]

TYKERB gives you and your patients a new way to suppress HER2 receptors by working intracellularly to inhibit the tyrosine kinase components of EGFR and

HER2 receptors, commonly associated with breast cancer cell proliferation and tumor growth.[1]

This approval was based on the pivotal Phase III trial of 399 patients which showed that the median time to disease progression as assessed by independent reviewers was 27.1 weeks on the combination of TYKERB and capecitabine versus 18.6 weeks on capecitabine alone in women with advanced or metastatic HER2 (ErbB2) positive breast cancer whose disease had progressed following treatment with trastuzumab and other cancer therapies. The hazard ratio of 0.57 (95% CI: 0.43, 0.77, p = 0.00013) represents a 43 percent reduction in the risk of progression for the patients on the combination arm.1 Differences between treatment groups based on unblinded investigator assessments were smaller but continued to be clinically and statistically significant.

Adverse events (AEs) leading to discontinuation were similar in the TYKERB-capecitabine combination arm (16 percent) versus capecitabine alone (13 percent). Most commonly reported AEs in the TYKERB-capecitabine combination arm included diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue. Left ventricular ejection fraction (LVEF), a measure of the strength of the heart's pumping capacity, was monitored during the study. Among 198 patients who received the TYKERB-capecitabine combination treatment, three experienced an asymptomatic (grade 2) decrease in LVEF and one experienced a symptomatic (grade 3) decrease in LVEF.

To support patient access, GlaxoSmithKline has established a single source for information and support called the Tykerb® CARES program. Through this comprehensive program, knowledgeable consultants are available to offer support for treatment adherence by providing product-related information to patients before they start their therapy. These consultants are also available to answer any questions doctors and patient advocates may have about TYKERB. Additionally, Tykerb® CARES reimbursement counselors will help patients understand their insurance coverage and, if appropriate, assist in identifying alternative financial support. More information regarding Tykerb® CARES can be found by calling 1-866-4-TYKERB. Program hours are Monday to Friday, 8:30 AM to 8:00 PM ET.

Sincerely,

Paolo Paoletti, MD
Senior Vice President
Oncology Medicine Development Center
GlaxoSmithKline

Please click the link below to to read full U.S. Prescribing Information

for Tykerb® (lapatinib).
http://www.elabs7.com/ct.html?rtr=on&s=av46,2ur3,2cv,79uh,jnhx,18pr,io7q

Please click the link below to review P4 Healthcare's Privacy Policy.
http://www.elabs7.com/ct.html?rtr=on&s=av46,2ur3,2cv,h2c5,bb1r,18pr,io7q

Please click the link below to review P4 Healthcare'sTerms and Conditions.
http://www.elabs7.com/ct.html?rtr=on&s=av46,2ur3,2cv,dvjg,bmkk,18pr,io7q

P4 Healthcare LLC
6031 University Blvd.
Suite 235
Ellicott City, MD 21043

Tykerb®
(lapatinib)

March 2007

Dear Doctor,

GlaxoSmithKline is pleased to announce the availability of Tykerb® (lapatinib).

TYKERB is indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.[1]

TYKERB gives you and your patients a new way to suppress HER2 receptors by working intracellularly to inhibit the tyrosine kinase components of EGFR and HER2 receptors, commonly associated with breast cancer cell proliferation and tumor growth.[1]

This approval was based on the pivotal Phase III trial of 399 patients which showed that the median time to disease progression as assessed by independent reviewers was 27.1 weeks on the combination of TYKERB and capecitabine versus 18.6 weeks on capecitabine alone in women with advanced or metastatic HER2 (ErbB2) positive breast cancer whose disease had progressed following treatment with trastuzumab and other cancer therapies. The hazard ratio of 0.57 (95% CI: 0.43, 0.77, $p = 0.00013$) represents a 43 percent reduction in the risk of progression for the patients on the combination arm.[1] Differences between treatment groups based on unblinded investigator assessments were smaller but continued to be clinically and statistically significant.

Adverse events (AEs) leading to discontinuation were similar in the TYKERB-capecitabine combination arm (16 percent) versus capecitabine alone (13 percent). Most commonly reported AEs in the TYKERB-capecitabine combination arm included diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue. Left ventricular ejection fraction (LVEF), a measure of the strength of the heart's pumping capacity, was monitored during the study. Among 198 patients who received the TYKERB-capecitabine combination treatment, three experienced an asymptomatic (grade 2) decrease in LVEF and one experienced a symptomatic (grade 3) decrease in LVEF.

To support patient access, GlaxoSmithKline has established a single source for information and support called the Tykerb® *CARES* program. Through this comprehensive program, knowledgeable consultants are available to offer support for treatment adherence by providing product-related information to patients before they start their therapy. These consultants are also available to answer any questions doctors and patient advocates may have about TYKERB. Additionally, Tykerb® *CARES* reimbursement counselors will help patients understand their insurance coverage and, if appropriate, assist in identifying alternative financial support. More information regarding Tykerb® *CARES* can be found by calling 1-866-4-TYKERB (89-5372). Program hours are Monday to Friday, 8:30 AM to 8:00 PM ET.

Sincerely,

Paolo Paoletti, MD
Senior Vice President
Oncology Medicine Development Center
GlaxoSmithKline

Please see accompanying complete Prescribing Information.

Reference: 1. TYKERB [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007.

gsk GlaxoSmithKline
Oncology

Tykerb® *CARES*
(lapatinib)

/alert Marketing
A Johnson Medical Information Company
7716 Kester Avenue
Van Nuys, CA 91405

Tykerb® (lapatinib)

Now FDA Approved!

GlaxoSmithKline
Oncology

M.D./alert®

TKB131R0

Tykerb®
(lapatinib)

March 2007

Dear Oncology Nurse,

GlaxoSmithKline is pleased to announce the availability of Tykerb® (lapatinib).

TYKERB is indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.[1]

This approval was based on the pivotal Phase III trial of 399 patients which showed that the median time to disease progression as assessed by independent reviewers was 27.1 weeks on the combination of TYKERB and capecitabine versus 18.6 weeks on capecitabine alone in women with advanced or metastatic HER2 (ErbB2) positive breast cancer whose disease had progressed following treatment with trastuzumab and other cancer therapies. The hazard ratio of 0.57 (95% CI: 0.43, 0.77, $p = 0.00013$) represents a 43 percent reduction in the risk of progression for the patients on the combination arm.[1] Differences between treatment groups based on unblinded investigator assessments were smaller but continued to be clinically and statistically significant.

Adverse events (AEs) leading to discontinuation were similar in the TYKERB-capecitabine combination arm (16 percent) versus capecitabine alone (13 percent). Most commonly reported AEs in the TYKERB-capecitabine combination arm included diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue. Left ventricular ejection fraction (LVEF), a measure of the strength of the heart's pumping capacity, was monitored during the study. Among 198 patients who received the TYKERB-capecitabine combination treatment, three experienced an asymptomatic (grade 2) decrease in LVEF and one experienced a symptomatic (grade 3) decrease in LVEF.

To support patient access, GlaxoSmithKline has established a single source for information and support called the Tykerb® *CARES* program. Through this comprehensive program, knowledgeable consultants are available to offer support for treatment adherence by providing product-related information to patients before they start their therapy. These consultants are also available to answer any questions doctors and patient advocates may have about TYKERB. Additionally, Tykerb® *CARES* reimbursement counselors will help patients understand their insurance coverage and, if appropriate, assist in identifying alternative financial support. More information regarding Tykerb® *CARES* can be found by calling 1-866-4-TYKERB (89-5372). Program hours are Monday to Friday, 8:30 AM to 8:00 PM ET.

Sincerely,

Paolo Paoletti, MD
Senior Vice President
Oncology Medicine Development Center
GlaxoSmithKline

Please see accompanying complete Prescribing Information.

Reference: 1. TYKERB [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2007.

gsk GlaxoSmithKline
Oncology

Tykerb® *CARES*
(lapatinib)

/alert Marketing
A Jobson Medical Information Company
7716 Kester Avenue
Van Nuys, CA 91405

Tykerb® (lapatinib)

Now FDA Approved!

GlaxoSmithKline
Oncology

Nurse/alert®

TKB130R0