

PHARMACY CORNER

Bevacizumab Approved for Use in Renal Cell Carcinoma



Bevacizumab (Avas-
tin®, Genentech, Inc.),
a vascular endothelial
growth factor recep-
tor inhibitor, has been
granted U.S. Food and
Drug Administration
(FDA) approval for use in combina-
tion with interferon alpha therapy for
the treatment of metastatic renal cell
carcinoma. Approval was based on the
results of a randomized, double-blind,
placebo-controlled trial of patients
with metastatic renal cell carcinoma
(N = 649). Patients in the bevacizumab
plus interferon arm (n = 327) demon-
strated a significant improvement in
progression-free survival (10.2 months
versus 5.4 months) compared to patients
receiving interferon plus placebo (n =
322, $p < 0.0001$). However, no signifi-
cant improvement was seen in overall
survival.

Serious adverse events were more
common in the bevacizumab arm (31%
versus 19%). Bleeding, hypertension,
proteinuria, and thrombosis were among
the symptoms attributed to the addition
of bevacizumab. Fatal hemorrhaging,
gastric perforations, and complications
with wound healing have all occurred
with the use of bevacizumab. When pos-
sible, bevacizumab therapy should not
be initiated within 28 days of surgical
procedures.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm176025.htm.

Thalidomide Disappointing in Small Cell Lung Cancer Test

As reported by Lee et al. (2009), thali-
domide failed to show a survival benefit
when added to chemotherapy in treat-
ing small cell lung cancer (SCLC). All
patients (N = 724) in the phase III trial re-
ceived standard chemotherapy of carbo-
platin and etoposide every three weeks
for up to six cycles. Patients also were
randomized to receive either placebo or
thalidomide 100–200 mg daily for up to
two years. SCLC is a very vascular dis-

ease, and it had been hoped that the anti-
angiogenic agent thalidomide would be
a beneficial addition to standard therapy.
Use of thalidomide was associated with
an increased incidence of thrombotic
events compared to placebo (19% versus
10%, $p < 0.001$).

Lee, S.M., Woll, P.J., Rudd, R., Ferry, D.,
O'Brien, M., Middleton, G., et al. (2009).
Anti-angiogenic therapy using thalido-
mide combined with chemotherapy in
small cell lung cancer: A randomized,
double-blind, placebo-controlled trial.
Journal of the National Cancer Institute,
101(15), 1049–1057.

Cetuximab and Panitumumab Labeling Undergoes Changes



Research regarding
K-ras mutations has
provided insight into
why some patients
with tumors overex-
pressing epidermal
growth factor receptor
(EGFR) have failed to
respond to anti-EGFR
therapy. Labeling of
both cetuximab (Er-
bitux®, Imclone Sys-
tems) and panitumumab (Vectibix®,
Amgen, Inc.) has changed to reflect
the lack of benefit in treating colorectal
tumors demonstrating *K-ras* mutations
in codon 12 or 13. Both cetuximab and
panitumumab are EGFR antagonist
monoclonal antibody drugs.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm172905.htm.

Pemetrexed Receives Approval as a Maintenance Therapy



Pemetrexed (Al-
imta®, Eli Lilly & Co.)
has received FDA ap-
proval as maintenance
therapy in the treat-
ment of stage IIIb/IV
non-squamous non-small cell lung
cancer that has not progressed after
completion of four cycles of standard
platinum-based chemotherapy regi-
mens. Approval was based on a demon-
strated improvement in overall survival
of patients treated with pemetrexed
(n = 441) versus placebo (n = 222). Pa-

tients with non-squamous cell histolo-
gies showed a median overall survival
of 15.5 months compared to 10.3 months
in the placebo arm. However, patients
with squamous cell histologies fared
worse when treated with pemetrexed.
These patients had a median overall
survival of 9.9 months compared to 10.8
months in the placebo arm.

Pemetrexed was dosed at 500 mg/m²
IV over 10 minutes in 21 day cycles until
disease progression. Patients were sup-
ported with folic acid, vitamin B₁₂, and
corticosteroid therapy to minimize the
toxicities of pemetrexed.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm170660.htm.

Fentanyl Buccal Film Now Used to Treat Breakthrough Pain

A buccal film formulation of fentanyl
(Onsolis®, Meda Pharmaceuticals) has
received FDA approval as an opioid an-
algesic for breakthrough pain in patients
who are already receiving around-the-
clock opioid therapy and who also are
opioid-tolerant.

Currently only available by prescrip-
tion through a restricted distribution
program, the FDA is requiring continued
evaluation of Onsolis to ensure that
benefits outweigh the risks associated
with use of Onsolis. The drug comes as a
small film that dissolves in 15–30 seconds
when placed along the mucosal lining of
the cheek. It is available in doses from
200–1,200 mcg.

For more information, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm172366.htm.

SAFETY UPDATE

Electronic Cigarettes Draw Criticism, Concern

The FDA has expressed concern re-
garding the safety of electronic cigarettes,
or e-cigarettes. These battery operated
nicotine-delivery products, available in
flavors such as chocolate, strawberry,
and mint, are seen by some as being
marketed to children. The products do
not require the same kinds of warning
labels as traditional tobacco products