20th Expert Committee on Selection and Use of Essential Medicines

Peer Review Report #1

Non-Small Cell Lung Cancer (NSCLC)

Proposed medicines(s) for treatment of NSCLC (refer to application for specific protocols):

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Currently on EML</th>
<th>Addition</th>
</tr>
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<tbody>
<tr>
<td>vinorelbine</td>
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<tr>
<td>cisplatin</td>
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<tr>
<td>etoposide</td>
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<tr>
<td>gemcitabine</td>
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<td>paclitaxel</td>
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<tr>
<td>carboplatin</td>
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<tr>
<td>erlotinib</td>
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<td>gefitinib</td>
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</table>

(1) Does the application adequately address the issue of the public health need for the treatment of the disease?

Yes ☒ No ☐

Comments: Exec summary needs to make it clear that since 2008, the simple pathologic separation of NSCLC from SCLC is no longer adequate for determining treatment decisions for local advanced or stage IV lung cancer. Pathologists must separates squamous (26% of NSCLC) from non-squamous (includes adenocarcinoma accounts for 35-40% of cases of NSCLC, large cell 25%). Molecular testing (for EGFR or ALK rearrangements) is only appropriate in non-squamous NSCLC. This information on histology also needs to be included on page 3 just before the sentence beginning “Molecular testing is crucial.”.

(2) Have all important studies that you are aware of been included in the application?

Yes ☒ No ☐

Comments:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the proposed treatment regimen(s)?

Yes ☒ No ☐

Given the choices of vinorelbine, gem and paclitaxel suggest delete etoposide.

(4) Does the application provide adequate evidence of safety for the proposed treatment regimen(s)? Are there any adverse effects of concern, or that may require special monitoring?

Yes ☒ No ☐

Comments:

ADDITIONAL CONSIDERATIONS:

(5) Are there special requirements or training needed for the safe, effective and/or appropriate use of the proposed treatment(s)?

Yes ☐ No ☒

Comments:

(6) Are there any issues regarding the registration of the proposed medicines by regulatory authorities? (e.g., recent registration, new indications, off-label use)

Yes ☐ No ☒

Comments:

(7) Comment briefly on issues regarding cost and affordability of treatment.

Cytotoxics doublets are cost effective. TKIs are marginal.

(8) Any additional comments on the application?

(9) Please summarise the action(s) you propose the Expert Committee take.

Support cytotoxics and TKIs. Pemetrexed should also be considered.