7. Clinical Studies with Epothilones

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7.1. Introduction

As indicated in previous chapters, epothilone research so far has delivered seven new chemical entities that have been advanced to clinical trials in humans (Fig. 1). However, the amount of clinical data publicly available at this time strongly varies between individual compounds, depending on their development stage, but also on the general publication policy of the developing company. The compound that has been most comprehensively characterized in the clinical literature is ixabepilone (BMS-247550), for which trial results have been described in a number of articles in peer-reviewed journals and which has been granted FDA approval for two clinical indications on Oct. 16, 2007. For all other compounds, most of the information on clinical trials is available only in abstract form. In all these cases it remains uncertain, whether the content of these abstracts fully reflects the content of the
subsequent (poster or oral) presentations at the corresponding meeting; in fact, it seems likely that additional data will have been included in the actual meeting presentations that may not have been available at the time of abstract submission. As this is unknown to the author, such additional information cannot be considered in this chapter, which is solely based on information documented in accessible abstracts or journal publications. It should also be kept in mind that the interpretation of data from ongoing clinical trials or forward looking statements based on data from completed trials are always preliminary in character. Compounds that may appear promising at the time of writing of this article may still fail in further development and have been abandoned by the time of publication of this chapter.

The most advanced epothilone in clinical development at this point is the Epo B lactam ixabepilone, which has recently received FDA approval for the treatment of metastatic or advanced breast cancer, either as single agent or in combination with capecitabine, and will be marketed in the US by Bristol-Myers Squibb (BMS) under the trade name Ixempra® (1). Based on information from the Novartis webpage, Phase III trials are also ongoing with patupilone in ovarian cancer (2). Data from Phase II studies (as the highest phase investigated) have been

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