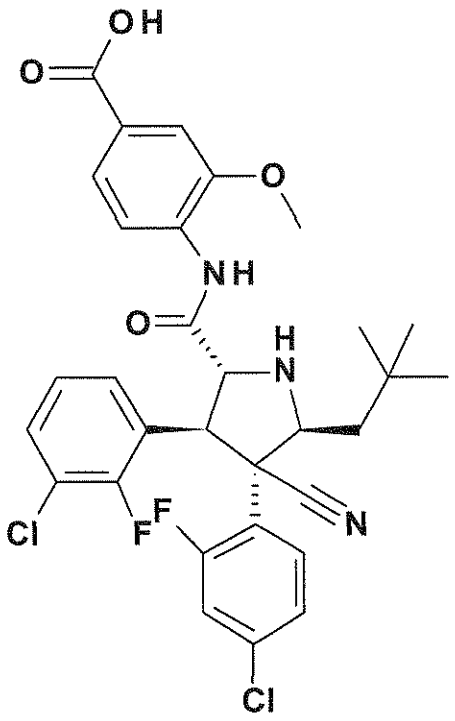
induces cell cycle arrest and/or apoptosis in a variety of tumor types expressing wild-type p53 in vitro and in vivo. Compound (1) belongs to a novel class of MDM2 inhibitors having potent anti-cancer therapeutic activity, in particular in leukemia such as acute myeloid leukemia (AML) and solid tumors such as for example head and neck, non-small cell lung, breast and colorectal cancers, as well as sarcoma.

The above-identified international patent application and US Patent describe Compound A in crystalline form and is herein incorporated by reference in its totality. The crystalline form of the compound has an on-set melting point of approximately 277 °C. The crystalline forms have relatively low aqueous solubility (<0.05 μg/mL in water) at physiological pHs (which range from pH1.5-8.0) and consequently less than optimal bioavailability (high variability). It is thus desirable to obtain a form of the compound which has improved solubility/dissolution rate and bioavailability.

Active pharmaceutical ingredients (API's) may be prepared in a variety of different forms, such as for example salts, solvates, hydrates, co-crystals. API's may also be in their amorphous state or one or several crystalline forms (polymorphs). Depending on the form, the physicochemical properties of an API may change, leading to e.g. different solubility, thermodynamic stability, density or melting point of different forms. Such physicochemical properties therefore may have significant influence of the efficacy or bioavailability of a known API.

SUMMARY

In one aspect, the present disclosure provides solid forms of compound (1)



selected from the group consisting of,

a) a substantially amorphous form of compound (1);

b) a hemi-hydrate, hydrate, hemi-solvate or solvate of compound (1);

c) a polymorph of compound (1); or

d) a pharmaceutically acceptable salt of compound (1).

In one particular embodiment, said solid form is selected from a hemi-hydrate or -solvate designated form IV, V, VI, VII of compound (1).

In another particularly preferred embodiment, said solid form is selected from a polymorph designated form I, II and III of compound (1).

In yet another preferred embodiment, said solid form is selected from the substantially amorphous form of compound (1).

In another embodiment, the disclosure provides a method of for treating a disease or condition in a mammal in need thereof. The method includes administering to the mammal an effective amount of a composition comprising a solid form compound as described herein.

In another aspect, the present disclosure relates to a pharmaceutical composition comprising one or several solid forms as disclosed herein, together with pharmaceutically acceptable adjuvants or excipients.

The solid forms disclosed herein may be further processed into any type of solid pharmaceutical preparations or dosage forms, which are known to the person of skill in the art. Particularly preferred are oral dosage forms such as tablets, capsules, pills, powders, suspensions, pasts and the like. Detailed descriptions of suitable excipients as well as methods for making such pharmaceutical preparations can for example be found in: Raymond C. Rowe et al, *Handbook of Pharmaceutical Excipients, 6th edition*, **2009**, Pharmaceutical Press (Publ.); ISBN-10: 0853697922.

Consequently, so obtained pharmaceutical preparations form further embodiments provided herein.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1: FTIR spectra of amorpheous form of compound (1);

Fig. 2: FTIR spectra of Form I of compound (1);

Fig. 3: FTIR spectra of Form III of compound (1);

Fig. 4: FTIR spectra of Form IV of compound (1);

Fig. 5: FTIR spectra of Form V of compound (1);

Fig. 6: FTIR spectra of Form VI of compound (1);

Fig. 7: FTIR spectra of Form VII of compound (1);

Fig. 8: XRPD curve of Form I of compound (1);