

<안전성유효성 심사관련 제출 자료 목록>

- 한국노바티스(주), “아피니토정 5밀리그램, 10밀리그램”

○ 관련규정 : 의약품등의 품목허가신고심사 규정(제2008-56호, 2008.8.14) 제2조제8호 및 제5조제2항 [별표1]II.2. 새로운 효능군 의약품

구분	제출자료																		자료 번호 주1)	
	1	3				4						5			6		7	8		
		가		나		가	나	다	라	마	바			가	나	다			가	나
1)	2)	1)	2)	(1)	(2)						(3)									
II.자료제출의약품 1. 새로운 효능군																				
자료범위	○	×	×	○	○	×	×	×	×	×	△	△	△	○	△	△	○	×	○	○
제출여부	○	×	×	○	○	×	×	×	×	×	×	×	×	○	○	×	○	×	○	○

○ 제출자료목록

1. 기원, 발견 및 개발경위에 관한 자료

3. 안정성에 관한 자료

- 가. 장기보존시험 : 18개월 장기보존 시험자료
- 나. 가속시험 : 6개월 가속시험 자료
- 다. 가혹시험 : 온도, 가혹시험 자료

5. 약리작용에 관한 자료

가. 효력시험

- 1) RAD001 inhibits the growth factor-stimulated activation of p70 S6 kinase
- 2) The in vitro antiproliferative activity of RAD001 against a panel of breast, NSCLC and renal tumor lines
- 3) In vitro activity of RAD001 in tumor cells derived from patient-derived tumor xenografts
- 4) Determination of the anti-tumor activity of RAD001 against a broad variety of tumor xenografts established by direct transplanation of human tumor material to immunosuppressed mice
- 5) RAD001 is an effective agent against renal cell tumor xenograft established by direct transplantation of human tumor material to immunosuppressed mice
- 6) Molecular analysis of a panel of tumor cell lines with known response to RAD001 in vitro

**나. 일반약리시험(또는 안전성약리시험) :**

- 1) General pharmacology of SDZ RAD
- 2) Effect of RAD N BHT on action potential parameters in sheep isolated cardiac purkinje fibres)
- 3) Cardiovascular effects of RAD in anesthetized pigs
- 4) Effect of RAD on lung function in the guinea-pig
- 5) Primary observation test of RAD001
- 6) Electrophysiological safety measurements of hERG currents in stably transfected HEK293 cells

**6. 임상시험에 관한 자료**

- 1) A phase I study investigating RAD001 as monotherapy in patients with advanced solid tumors
- 2) A phase 1b study investigating safety, tolerability and molecular pharmacodynamic effects of RAD001 monotherapy in patients with solid cancers
- 3) A phase I dose-escalation study of RAD001 administered daily in patients with advanced solid tumors
- 4) A blind, randomized, placebo and active controlled, singled-dose crossover study to investigate the effect of RAD001 on cardiac intervals in healthy volunteers
- 5) A randomized, double-blind, placebo-controlled, multicenter phase III study to compare the safety and efficacy of RAD001 plus Best Supportive Care (BSC) versus BSC plus placebo in patients with metastatic carcinoma of the kidney which has progressed on VEGF receptor tyrosine kinase inhibitor therapy

**7. 외국의 사용현황에 관한 자료 : 미국**

**8. 국내유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료 끝.**